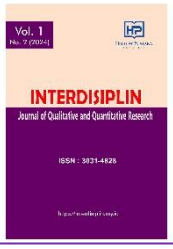

INTERDISIPLIN
Journal of Qualitative and Quantitative Research

ISSN: 3031-4828
DOI: https://doi.org/10.61166/interdisiplin.v3i3.155

Vol. 3 No. 3 (2026)
pp. 205-223

Research Article

Recent Developments in the Therapeutic Management of Diabetes Mellitus

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Received	: February 17, 2026	Revised	: March 15, 2026
Accepted	: April 13, 2026	Available online	: May 31, 2026

How to Cite: Fraidoon Farzam, & Aliseena Yussufpur. (2026). Recent Developments in the Therapeutic Management of Diabetes Mellitus. *INTERDISIPLIN: Journal of Qualitative and Quantitative Research*, *3*(3), 205–223. https://doi.org/10.61166/interdisiplin.v3i3.155

Abstract. Diabetes mellitus (DM) represents a growing global health concern, imposing a substantial socio-economic burden on healthcare systems worldwide. Conventional therapeutic strategies have demonstrated limited success in addressing the multifactorial etiology of DM and are frequently associated with significant adverse effects. Consequently, there has been a surge in the development and evaluation of novel therapeutic modalities. This narrative review critically examines recent advancements in DM treatment and the associated implementation challenges. A comprehensive literature search was conducted using databases such as Web of Science, PubMed/MEDLINE, and Scopus, employing keywords including “diabetes mellitus,” “management of diabetes,” and “gene therapy.” Emerging evidence indicates considerable progress in DM management through innovative approaches such as nanotechnology-based drug delivery systems, gene therapy, stem cell therapy, medical nutrition therapy, and lifestyle interventions. Despite these advancements, several challenges persist, including the need for optimization of these therapies to achieve effective glycemic, lipid, and blood pressure control; enhancement of patient adherence to therapeutic regimens; safety and ethical

considerations; and the development of efficient delivery systems. In conclusion, the integration of lifestyle modifications with pharmacological and emerging therapeutic strategies, along with their continued refinement, is essential for the establishment of safe, effective, and individualized clinical management protocols for diabetes mellitus.

Keywords: diabetes mellitus, Gene therapy, stem cell therapy, nanotechnology, lifestyle modification

INTRODUCTION

Diabetes mellitus (DM) is a chronic, multifactorial, and non-communicable endocrine disorder characterized by persistent hyperglycemia resulting from defects in insulin secretion, insulin action, or both. It represents a growing global health concern, posing substantial clinical and socio-economic challenges due to its progressive nature and association with multiple metabolic disturbances. The pathophysiology of DM involves not only sustained elevations in blood glucose and lipid levels but also increased oxidative stress, which collectively contribute to long-term complications affecting various organ systems—most notably the kidneys, eyes, peripheral nerves, and vascular structures. According to the World Health Organization (WHO), DM constitutes a global epidemic with significant morbidity and mortality. As of recent estimates, over 387 million individuals are affected worldwide, a figure projected to rise to approximately 640 million by the year 2040 [1]. Complementing this, the International Diabetes Federation (IDF) reported in 2017 that approximately 425 million individuals were living with diabetes, with over 90% of these cases occurring in adults. Moreover, an estimated 352 million people exhibited impaired glucose tolerance (IGT), placing them at elevated risk for developing type 2 diabetes mellitus (T2DM) [2]. T2DM is associated with a broad spectrum of comorbidities, including nephropathy, retinopathy, cardiovascular disease, cerebrovascular accidents, and lower limb amputations [3]. While the hyperglycemic state remains a defining clinical feature, mounting epidemiological evidence suggests that T2DM is a polygenic disorder influenced by complex genetic and environmental interactions [4]. In contrast, individuals with type 1 diabetes mellitus (T1DM) face distinct challenges, particularly the risk of hypoglycemia, which significantly impedes the attainment of optimal glycemic control [5]. A subset of T1DM patients also suffers from impaired hypoglycemia awareness, further complicating disease management and increasing vulnerability to severe glycemic excursions [6]. Despite advances in our understanding of DM pathogenesis and the development of exogenous insulin formulations and analogues, achieving stringent glycemic control without inducing adverse effects—such as hypoglycemia or weight gain—remains a clinical obstacle [7,12,13]. Insulin therapy continues to be the cornerstone in the treatment of insulin-deficient states, particularly in T1DM, due to the absolute deficiency of pancreatic beta-cell function [11]. Nevertheless, the limitations of current pharmacologic strategies underscore the imperative to explore adjunctive or alternative therapeutic modalities [14]. Accordingly, this narrative review aims to synthesize current progress in the development of innovative therapeutic strategies for both T1DM and T2DM. Special emphasis is placed on

emerging modalities such as nanotechnology, gene therapy, stem cell technology, medical nutrition therapy, and lifestyle modification. The review also critically appraises the inherent challenges associated with the clinical application and optimization of these novel approaches.

METHODS

A comprehensive literature search was conducted to identify relevant publications pertaining to recent advancements in the management of diabetes mellitus (DM). This narrative review utilized multiple academic databases, including Scopus, PubMed/MEDLINE, Web of Science, and Google Scholar. The search strategy incorporated a combination of keywords and subject headings, such as diabetes mellitus, hyperglycemia, type 2 diabetes mellitus (T2DM), DM management, nanotechnology in diabetes, gene therapy in DM treatment, and current therapeutic approaches. Titles and abstracts yielded from the search were meticulously screened for relevance, and studies meeting the inclusion criteria were selected for full-text review. The selection process was performed independently by three reviewers to ensure objectivity and minimize selection bias. Eligible studies included original research articles and review papers published in English between 1993 and 2022. Non-peer-reviewed materials, including unpublished manuscripts and theses, were excluded from the analysis. Following full-text assessment, only studies that met the predefined criteria and demonstrated methodological rigor were incorporated into the final synthesis. All included studies were independently validated by the authors to ensure the accuracy and reliability of the review findings.

Predisposing factors of diabetes

Numerous risk factors have been identified as contributing to the onset and progression of diabetes mellitus (DM). These factors not only influence disease susceptibility but also affect its clinical trajectory. Key risk factors include advancing age, increased body weight, family history of diabetes, tobacco use, and racial or ethnic background [15, 16]. Type 1 diabetes mellitus (T1DM) is predominantly diagnosed in younger individuals and is largely autoimmune in origin. In contrast, type 2 diabetes mellitus (T2DM) is typically associated with adulthood and its prevalence increases with advancing age. This trend is primarily attributed to age-related declines in pancreatic β-cell function and progressive insulin resistance, which are often linked to changes in body composition and reduced physical activity [17]. Obesity, particularly central adiposity, is one of the most significant modifiable risk factors for T2DM. The strong association between increased body mass index (BMI) and insulin resistance has given rise to the term “diabesity,” underscoring the pathophysiological interconnection between obesity and diabetes [18]. Excess adipose tissue contributes to a chronic inflammatory state and hormonal imbalances that exacerbate insulin resistance and impair glucose metabolism. Smoking is another critical modifiable risk factor. According to the U.S. Food and Drug Administration (FDA), smokers have a 30–40% higher likelihood of developing T2DM compared to non-smokers. Nicotine and other tobacco-related compounds have been shown to impair insulin sensitivity, thereby increasing the need for exogenous insulin and

complicating glycemic control [19]. Genetic predisposition also plays a pivotal role in the development of DM. Individuals with a first-degree relative affected by diabetes are at a significantly increased risk of developing the disease. Although genetic factors are non-modifiable, early lifestyle interventions—such as dietary modification, physical activity, and weight management—are strongly recommended for at-risk populations to mitigate disease onset and progression.

Modern Therapeutic Interventions in Diabetes

The effective management of diabetes mellitus (DM) requires a multifaceted approach incorporating early diagnosis, individualized treatment plans, and evidence-based therapeutic strategies. Timely diagnosis is fundamental to the successful implementation of disease management protocols and is critical in preventing or delaying the onset of complications associated with both type 1 and type 2 diabetes mellitus [20]. Management goals are typically established at the initial clinical encounter and tailored to the specific needs, comorbidities, and lifestyle factors of each patient, thereby promoting a personalized medicine framework.

1. Web-Based Approaches to Promote Healthy Lifestyles for diabetes

Lifestyle modification remains a cornerstone in the management of both pre-diabetes and diabetes. Interventions aimed at reducing sedentary behavior, increasing physical activity, and improving dietary habits are widely recommended and have demonstrated significant efficacy in glycemic control and overall metabolic health. The specific form and intensity of physical activity are often determined based on the individual's health status, with aerobic and resistance exercises shown to be effective in lowering plasma glucose levels. Nutritional strategies for individuals with diabetes typically emphasize the consumption of fiber-rich vegetables, fruits, and whole grains; the inclusion of low-fat dairy products and lean protein sources; and the limitation of foods high in saturated fats, added sugars, and refined carbohydrates. Additional lifestyle interventions include smoking cessation and the reduction of alcohol intake, both of which are associated with improved glycemic outcomes and reduced cardiovascular risk [21,22]. These lifestyle modifications are most effective when customized to the patient's clinical profile and socio-behavioral context [23].

2. Applications of Nanotechnology in Diabetes Care

Nanotechnology, defined by the manipulation of matter at dimensions typically less than 100 nanometers, has emerged as a transformative tool in the field of biomedicine. The application of nanotechnology in medical science—commonly referred to as nanomedicine—has facilitated significant advancements in drug delivery, diagnostics, and disease monitoring. In the context of diabetes mellitus (DM), nanomedicine has shown considerable promise in enhancing both diagnostic precision and therapeutic outcomes through the development of nanoscale devices for glucose sensing and insulin administration [24, 25]. Nanotechnology facilitates site-specific drug delivery by incorporating nanoscale carriers capable of targeting particular tissues or cells. In diabetes management, these technologies have enabled

the non-invasive delivery of insulin and the development of novel therapeutic strategies, including cell-based and gene-based interventions, particularly in type 1 diabetes mellitus (T1DM) [24]. Furthermore, nanotechnology has been instrumental in advancing glucose monitoring systems and improving early diagnosis by detecting immune activity and quantifying pancreatic beta-cell mass. Early and accurate diagnosis is critical in preventing the progression of dysglycemia and delaying the onset of overt diabetes. While traditional diagnostic methods—such as plasma glucose measurements and autoantibody detection—are widely utilized, they often lack the sensitivity and specificity required for early-stage detection. Nanotechnology-based imaging, particularly the use of magnetic nanoparticles (MNPs), offers enhanced diagnostic capabilities. MNPs possess unique magnetic properties, making them highly effective as contrast agents in magnetic resonance imaging (MRI). This enables the early identification of beta-cell destruction, a hallmark of T1DM progression, thereby allowing timely clinical intervention [26, 27]. Maintaining stable glycemic control is essential to minimizing the risk of diabetes-related complications. Regular blood glucose monitoring is critical in this regard; however, conventional self-monitoring methods—such as finger-prick tests—are often associated with poor adherence due to discomfort and inconvenience. These limitations hinder the ability to track glycemic fluctuations, particularly during periods such as sleep or physical activity, which can result in undetected hypoglycemia or hyperglycemia [28]. To address these challenges, continuous glucose monitoring (CGM) systems have been developed. While current CGM technologies—such as subcutaneous amperometric biosensors—have improved glycemic surveillance, they still present limitations, including sensor instability and the need for frequent replacement [29,30]. Nanotechnology offers a compelling solution to these shortcomings. Nanoscale glucose sensors, composed of key components such as detectors, transducers, and signal reporters, are engineered using glucose oxidase, glucose-binding proteins, or small glucose-binding molecules. These components collectively enable real-time, high-sensitivity glucose detection in a patient-friendly format [24, 31]. Insulin remains the cornerstone of therapy for individuals with T1DM and many with advanced T2DM. Traditional insulin delivery methods, primarily via subcutaneous injections, can be burdensome and may negatively impact patient adherence despite advancements in needle design [32]. Moreover, the pharmacokinetics of subcutaneous insulin injections often result in delayed onset and peak activity, creating a temporal mismatch between insulin action and glycemic needs, and contributing to glycemic variability [24]. In response, novel delivery systems—such as closed-loop microcomputer-controlled insulin pumps, also known as “artificial pancreas” systems—have been developed. These systems integrate continuous glucose monitoring with automated insulin delivery, enabling real-time modulation of insulin administration based on plasma glucose levels and significantly reducing glycemic excursions [26,33]. Furthermore, alternative, less invasive insulin delivery platforms using nanoparticles are under investigation. These include oral, transdermal, and inhalable formulations, which aim to improve bioavailability, reduce patient burden, and enhance compliance [26].

3. Nutritional Management in Diabetes Care

Medical Nutrition Therapy (MNT), defined as a nutrition-based clinical intervention provided by a registered dietitian nutritionist (RDN), represents a foundational component of comprehensive diabetes care. MNT encompasses individualized nutrition assessment, diagnosis, and evidence-based counseling tailored to optimize glycemic control, support metabolic health, and reduce diabetes-related complications. As a core pillar of diabetes self-management education and support (DSMES), MNT has been endorsed by numerous international guidelines as a critical strategy for mitigating the adverse consequences of poor dietary patterns and facilitating long-term disease control [34, 35]. In the management of gestational diabetes mellitus (GDM), MNT assumes heightened significance. Given that carbohydrate (CHO) intake exerts a direct influence on postprandial glycemia, dietary strategies that modulate carbohydrate quality and quantity are pivotal. According to the Institute of Medicine, pregnant individuals require a minimum daily intake of 175 grams of CHO to ensure adequate fetal growth and maternal energy needs [36]. Traditional approaches to GDM management have often employed moderate CHO restriction, which has been demonstrated to be both safe and effective in preventing ketogenesis and metabolic acidosis. Recent evidence further supports the use of low-glycemic index diets in improving glycemic outcomes in GDM; however, more robust, large-scale studies are needed to establish conclusive clinical guidelines [37]. Beyond GDM, MNT has demonstrated substantial efficacy in the management of both type 1 and type 2 diabetes mellitus. Key objectives of MNT include the achievement and maintenance of euglycemia, appropriate weight gain (in pregnancy), preservation of lean body mass, and prevention of diabetes-related complications. Nevertheless, there remains a lack of consensus regarding the optimal dietary pattern for individuals with diabetes in terms of macronutrient distribution, caloric intake, and food quality. This variability underscores the importance of a patient-centered approach, in which individualized meal planning takes into account cultural preferences, comorbid conditions, and behavioral readiness [37]. Caloric restriction remains an essential component of MNT in individuals with overweight or obesity, particularly given the strong association between excess adiposity, insulin resistance, and type 2 diabetes. Clinical trials have shown that moderate energy restriction, when combined with increased physical activity and behavioral strategies, can significantly improve glycemic control and reduce the need for pharmacologic therapy. Emerging consensus emphasizes the need for MNT protocols that are both evidence-based and adaptable to real-world clinical practice. Collaborative models involving diabetologists, endocrinologists, and RDNs are being advocated to ensure that dietary interventions are not only clinically sound but also feasible and sustainable for diverse patient populations [38]. A strategic focus on the development of personalized dietary frameworks—integrating both therapeutic goals and individual preferences—holds promise for enhancing adherence and clinical efficacy.

4. Gene-Based Therapies for Diabetes Mellitus

Gene therapy represents an innovative and evolving therapeutic approach that involves the correction of disease phenotypes through the introduction, modification,

or silencing of specific genes within target cells. Originally conceptualized as a means to replace defective genes with functional ones, contemporary gene therapy now encompasses a broader spectrum of molecular interventions—including gene addition, suppression, and precise genome editing—facilitated by technologies such as CRISPR-Cas9, zinc finger nucleases (ZFNs), and transcription activator-like effector nucleases (TALENs) [39–41]. The fundamental objective of gene therapy is to restore normal physiological function by addressing the genetic underpinnings of disease pathogenesis. Therapeutic strategies typically fall into three major categories: (i) insertion of functional genes to compensate for non-functional or missing genes, (ii) replacement of mutated genes with corrected variants, and (iii) suppression or inactivation of deleterious genes [42,43]. Based on the target cell population, gene therapy can be classified into somatic gene therapy—which targets non-reproductive (somatic) cells—and germline gene therapy, which involves modifications to germ cells and has the potential to transmit therapeutic effects across generations [43]. The applicability of gene therapy in diabetes mellitus (DM), particularly type 1 diabetes mellitus (T1DM), is under intense investigation due to the autoimmune nature of the disease and the limitations of conventional insulin-based therapies [44]. T1DM is characterized by T-cell-mediated autoimmune destruction of pancreatic β-cells, leading to absolute insulin deficiency and chronic hyperglycemia. Given the multifactorial etiology of T1DM, which includes both genetic predispositions and environmental triggers, gene therapy offers a potentially curative approach by targeting the underlying molecular mechanisms that initiate or perpetuate autoimmunity and β-cell dysfunction [45–47]. Recent advances have identified numerous genetic loci associated with susceptibility to T1 DM, including HLA class II alleles, the insulin gene (INS), PTPN22, and CTLA4, among others. These findings open avenues for therapeutic gene editing aimed at modulating immune responses or enhancing β-cell survival and function. Gene-based interventions are currently being explored to promote immune tolerance, regenerate endogenous β-cells, or enable non-β-cell-mediated insulin production through cellular reprogramming. While gene therapy research in diabetes has predominantly focused on T1DM, its relevance in type 2 diabetes mellitus (T2DM) is also gaining traction. T2DM is a polygenic and multifactorial disorder characterized by insulin resistance and progressive β-cell dysfunction. Genome-wide association studies (GWAS) have identified over 75 loci linked to T2DM, many of which influence insulin secretion, glucose metabolism, and inflammatory signaling pathways [46–48]. These loci offer novel therapeutic targets for gene-based modulation [49]. One notable example is the nucleotide-binding oligomerization domain-like receptor protein 3 (NLRP3), an inflammasome component implicated in pancreatic β-cell apoptosis and systemic inflammation. Preclinical studies have demonstrated that inhibition of NLRP3 activity reduces β-cell apoptosis, alleviates insulin resistance, and prevents T2DM development in murine models [50]. Other candidate genes include those involved in glucose transporter function, insulin receptor signaling, adipokine regulation, and oxidative stress responses. Collectively, these genetic targets underscore the potential for gene therapy to provide durable, personalized treatments for T2DM.A summary of therapeutic gene targets currently under investigation for diabetes is provided in

Table 1 [51], including genes that regulate glucose homeostasis, enhance insulin biosynthesis or sensitivity, and mitigate diabetic complications.

5. Exploring Stem Cell Applications in Diabetes Care

Conventional therapeutic strategies for diabetes mellitus (DM), particularly insulin administration and oral hypoglycemic agents, primarily manage hyperglycemia without addressing the underlying pathophysiology—namely, the loss or dysfunction of insulin-producing pancreatic β-cells. These interventions are often associated with limitations such as suboptimal glycemic control, patient non-compliance, and adverse effects. Consequently, there has been increasing interest in regenerative medicine-based alternatives, particularly stem cell therapy, which holds the potential to restore endogenous insulin production by regenerating functional β-cell mass [52]. One of the earliest cellular approaches involved pancreas or islet-cell transplantation to replace destroyed β-cells. However, the widespread application of this strategy has been constrained by the scarcity of suitable donor organs and the need for long-term immunosuppression. This has prompted research into generating β-like cells through the differentiation of stem cells, which may serve as a sustainable and renewable source of insulin-secreting cells for therapeutic purposes [52, 53]. Stem cell therapy for DM aims to replenish or replace defective pancreatic β-cells using pluripotent or multi-potent stem cells. Among the most widely studied are embryonic stem cells (ESCs), induced pluripotent stem cells (iPSCs), and adult stem cells, including mesenchymal stem cells (MSCs) and hematopoietic stem cells (HSCs). These cell types have demonstrated varying degrees of success in differentiating into insulin-producing cells either directly or through reprogramming and transdifferentiation protocols [53]. Technological advances have enabled the isolation and expansion of stem cells from diverse tissue sources, including adipose tissue, skin, bone marrow, umbilical cord blood, dental pulp, and periosteum. The pancreas remains a critical tissue of interest due to its direct involvement in insulin production. Preclinical studies in animal models have shown that even limited pancreatic tissue can contribute to the restoration of β-cell mass via mechanisms such as replication, dedifferentiation, and the reactivation of pluripotent phenotypes from ductal epithelium [54]. These ductal progenitors have also been cultured ex vivo and directed to differentiate into insulin-producing clusters, further supporting their potential as therapeutic substrates [55,56]. Adult stem cells, particularly MSCs and HSCs, have demonstrated remarkable plasticity and the capacity for transdifferentiation into various cell lineages, including neuronal, hepatic, pulmonary, and gastrointestinal cells [57–59]Several experimental studies have explored the use of hematopoietic progenitors to restore pancreatic β-cell mass. For example, murine bone marrow-derived cells have been successfully differentiated into insulin-producing cells ex vivo, with subsequent transplantation leading to normoglycemia in diabetic mice models [60,61]. Notably, bone marrow cells have also exhibited homing ability to pancreatic tissue, further enhancing their therapeutic relevance. Clinical investigations using autologous HSCs have yielded encouraging outcomes. In both T1DM and T2DM patients, autologous transplantation has been associated with improvements in glycemic parameters and reduced insulin

requirements, suggesting the restoration of β-cell function or modulation of autoimmune mechanisms [62,63].

6. New Developments in Diabetes Therapy

Beyond conventional and emerging treatment modalities, continuous advances in pharmacotherapy have significantly influenced the landscape of diabetes mellitus (DM) management. A number of novel agents have recently received regulatory approval, while others remain under investigation at various stages of clinical development. These innovations offer the potential to improve glycemic control, enhance patient adherence, and reduce the risk of complications in individuals with both type 1 (T1DM) and type 2 diabetes mellitus (T2DM).Gene Classification and Their Principal Roles in Glucose Homeostasis, Insulin Regulation, and Diabetes-Related Complications [51].

Genes Regulating Glucose Homeostasis

- GLUTs (Glucose Transporters): Mediate the reabsorption of filtered glucose from renal tubules back into systemic circulation.
- SGLTs (Sodium-Glucose Co-Transporters): Play a pivotal role in glucose flux across muscle and hepatic tissues.
- FGFs (Fibroblast Growth Factors): Crucial regulators of systemic glucose homeostasis.
- SIRT6 (Sirtuin 6): Involved in the regulation of GLUT expression and promotion of glycolytic activity.

Genes Enhancing Insulin Secretion and Sensitivity

- GLP-1 and Its Analogs/Agonists (Glucagon-Like Peptide-1): Promote β-cell survival, upregulate insulin gene expression, and stimulate insulin biosynthesis.
- GPCRs and Their Agonists (G Protein-Coupled Receptors): Augment insulin and GLP-1 secretion.
- CTB-APSL (Cholera Toxin B Subunit–Active Peptide Sequence Ligand): Facilitates insulin secretion and modulates insulin resistance.
- IKKε (IκB Kinase Epsilon) and TBK1 (TANK-binding kinase 1): Associated with reductions in adiposity, insulin resistance, hepatic steatosis, and systemic inflammation.

Genes Mitigating Diabetes-Induced Complications

- IL-1β (Interleukin-1 beta): Implicated in pro-inflammatory cascades and β-cell apoptosis.
- ADPN (Adiponectin): Exhibits renoprotective effects by ameliorating diabetic nephropathy.
- TGF-α (Transforming Growth Factor Alpha): Involved in diabetic kidney disease via nephron loss mechanisms.
- NLRP3 (NOD-, LRR- and pyrin domain-containing protein 3): Plays a protective role in diabetic cardiomyopathy.

- CDKN2A/2B (Cyclin-Dependent Kinase Inhibitors): Influence T-cell phenotypic modulation and chronic inflammatory responses.
- HSP70 (Heat Shock Protein 70): Regulates mitochondrial bioenergetics and is implicated in diabetic sensory neuropathy.

MicroRNAs: Modulate diabetic microvascular pathologies through post-transcriptional gene regulation

1. Latest Pharmacotherapy Approvals

- Tirzepatide: Tirzepatide, marketed under the trade name Mounjaro, was recently approved by the U.S. Food and Drug Administration (FDA) for the treatment of T2DM [64]. It is a once-weekly subcutaneous injectable that acts as a dual agonist at the receptors for glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP), two incretin hormones integral to glucose metabolism. GLP-1 enhances glucose-dependent insulin secretion, suppresses glucagon secretion during hyperglycemia, delays gastric emptying, and promotes satiety. GIP similarly promotes insulin secretion during hyperglycemia but also facilitates glucagon release during hypoglycemia [65].
- Tirzepatide mimics and prolongs the effects of these endogenous incretins by binding to and activating their respective receptors, thereby optimizing postprandial and fasting glucose levels. Clinical trials have demonstrated its superior efficacy compared to placebo, GLP-1 receptor agonists (e.g., semaglutide), and long-acting insulin analogs (e.g., insulin degludec and insulin glargine), both as monotherapy and in combination regimens. At its highest dose (15 mg), tirzepatide reduced glycated hemoglobin (HbA1c) by up to 1.5% more than placebo, 0.5% more than semaglutide, 0.9% more than insulin degludec, and 1.0% more than insulin glargine [64]. Its robust glycemic efficacy, coupled with the convenience of once-weekly administration, positions tirzepatide as a transformative agent in the management of T2DM.

2. Therapeutic Approaches in the Research Phase

Several novel drug candidates are currently in various phases of preclinical and clinical development. These agents aim to enhance glycemic control via diverse molecular targets and mechanisms of action.

- LY3502970: LY3502970 is a biased GLP-1 receptor (GLP-1R) agonist being developed by Eli Lilly. Unlike conventional GLP-1R agonists, it selectively favors G-protein signaling over β-arrestin recruitment, which may confer enhanced efficacy and reduced side effects. It exhibits high potency and selectivity within the class B G-protein-coupled receptor (GPCR) family and possesses favorable pharmacokinetic characteristics for oral administration—an important advancement in the delivery of GLP-1-based therapies [66].
- SCO-094: SCO-094 is a dual agonist targeting both GLP-1 and GIP receptors, developed by SCOHIA. This dual mechanism is similar in concept to tirzepatide and is expected to synergistically enhance glucose-dependent insulin secretion and metabolic regulation [67].
- Ladarixin (LDX): Ladarixin is an investigational compound developed by Dompé Farmaceutici that functions as a selective inhibitor of interleukin-8 (IL-8) receptors CXCR1 and CXCR2. It has been evaluated for its potential to preserve residual β-

cell function in newly diagnosed T1DM patients. Although short-term administration of Ladarixin demonstrated acceptable safety, it did not significantly alter the decline in β-cell function in early-phase clinical trials [68].

These agents represent promising avenues for advancing diabetes therapeutics. Their development reflects a broader shift toward mechanism-based and precision-oriented treatments capable of addressing the complex pathophysiology of DM.

Discussion of Significant Results

Diabetes mellitus (DM) is a chronic, multifactorial metabolic disorder characterized by progressive dysregulation of glucose homeostasis, which necessitates increasingly complex therapeutic strategies over time. The global research community has invested considerable effort in elucidating the pathophysiology of DM and developing novel therapeutic approaches. Substantial progress has been made in understanding the etiology and improving the management of type 1 diabetes mellitus (T1DM) [69]. Current evidence suggests that intensive insulin therapy, combined with self-monitoring of blood glucose, and adjunctive monitoring of blood pressure and lipid profiles, significantly enhances long-term outcomes in individuals with T1DM [70].

Lifestyle interventions, including structured physical activity and dietary modifications, play a critical role in improving quality of life and metabolic outcomes in individuals with diabetes. In cases where lifestyle interventions are insufficient or impractical, pharmacological therapies become essential for glycemic control. Moreover, advances in regenerative medicine, such as the implantation of insulin-producing cells, present a promising avenue to restore physiological glucose regulation, thereby mitigating long-term diabetic complications independent of exogenous hormone administration [71]. Gene therapy represents a frontier in diabetes research, with the potential to correct underlying genetic defects or restore β-cell function.

However, its clinical translation is hindered by several challenges, foremost among them being the need for safe, efficient, and cell-specific gene delivery systems. The successful development of such delivery systems, potentially using stem cell engineering, remains crucial. Strategies such as islet transplantation rejection suppression and insulin gene therapy, when used alongside conventional insulin regimens, have demonstrated effective glycemic control without inducing hypoglycemia in preclinical T1DM models [72]. Metabolic goals in diabetes management can be further supported by multifaceted lifestyle interventions. These include regulation of glycemic indices (fasting glucose, HbA1c), blood pressure, lipid profiles, and body weight, alongside evaluations of patient-reported quality of life metrics [73].

Nevertheless, many national healthcare systems focus disproportionately on managing diagnosed diabetes rather than preventing its onset. There is an urgent need for early detection programs targeting dysglycemia and for preventive measures addressing modifiable risk factors. Robust public health strategies encompassing improved diagnostics, early risk stratification, and risk mitigation could help reduce diabetes incidence and the progression to organ failure [73]. Beyond traditional

pharmacologic and lifestyle-based interventions, several advanced therapeutic strategies—such as nanotechnology, gene therapy, and stem cell therapy—have shown encouraging potential.

Nevertheless, these novel interventions are not without limitations. For instance, while continuous glucose monitoring (CGM) systems and insulin delivery technologies derived from nanomedical innovations provide real-time glycemic control, their high cost remains a barrier to widespread accessibility. Furthermore, the risk of infection associated with implanted sensors and cannulas contributes to patient reluctance and requires careful management [24]. Gene therapy approaches also face significant translational barriers. The use of viral vectors, while effective in enhancing gene delivery efficiency and long-term expression through genomic integration, may elicit immunogenic or inflammatory responses that exacerbate disease progression [74].

Additionally, most current gene therapy investigations remain in preclinical animal models, and their safety in humans is yet to be thoroughly validated [46]. The principal challenge in gene therapy lies in the development of reliable, specific, and safe gene delivery systems. While non-viral vectors offer advantages in terms of low immunogenicity, cost-effectiveness, and ease of production, their low transfection efficiency and transient gene expression limit their therapeutic utility [75]. Conversely, viral vectors—designed to retain only essential viral elements—demonstrate superior delivery capabilities but are associated with potential cytotoxicity, immunogenicity, and inflammation, necessitating further refinement for clinical application (45,75). Stem cell therapy, although highly promising, remains at an early developmental stage, burdened by technological and ethical constraints. For example, embryonic stem cells (ESCs) have the capacity to differentiate into insulin-producing β-cells; however, concerns regarding teratoma formation and malignancy hinder their clinical applicability (76) Rigorous preclinical assessment is essential to evaluate safety before translating ESC-based therapies into human trials. A primary barrier in stem cell-based transplantation is autoimmune rejection, necessitating the development of robust immunosuppressive protocols.

Furthermore, the survival, integration, and function of transplanted stem cells depend on the establishment of a supportive vascular and neural microenvironment. Additional challenges involve scalability and the capacity to generate sufficient quantities of functional cells for clinical use. This requires optimization of culture systems to ensure yield, stability, and reproducibility in large-scale production. The use of ESCs also raises profound ethical concerns. These cells are typically derived from surplus embryos obtained during in vitro fertilization procedures, with the procurement process often involving the destruction of the embryo. This presents a moral dilemma regarding the beginning of human life and the permissibility of embryo destruction for therapeutic purposes. In contrast, adult stem cells present fewer ethical challenges and are thus more acceptable for clinical research. Recent advances in induced pluripotent stem cell (iPSC) technology offer a viable alternative, allowing for the reprogramming of somatic cells into a pluripotent state and their subsequent differentiation into insulin-producing β-cells (77).This autologous

approach not only circumvents ethical controversies associated with ESCs but also potentially reduces the risk of immune rejection.

CONCLUSIONS

Diabetes mellitus (DM) continues to represent a formidable global public health challenge, with its prevalence rising at an alarming rate and projected to persist for several decades. Despite notable advances in therapeutic strategies, including pharmacological interventions, nanotechnology, gene therapy, and regenerative medicine, a definitive cure for DM remains elusive. Current treatment modalities, while effective in mitigating hyperglycemia and delaying complications, are often limited by issues such as cost, accessibility, adverse effects, or technological constraints. The complexity of DM, encompassing both its metabolic and systemic manifestations, necessitates a multifaceted and integrative approach to management. To achieve sustainable and effective control of the disease, it is imperative to address the limitations associated with each therapeutic strategy and refine existing modalities to enhance their efficacy, safety, and applicability across diverse populations. Optimal management of DM requires stringent regulation of key metabolic parameters, including blood glucose, blood pressure, and body weight. Achieving this entails not only clinical intervention but also sustained lifestyle modifications, including dietary improvement, regular physical activity, and behavioral support. These components are vital for improving insulin sensitivity, glycemic control, and overall patient outcomes. Furthermore, the effective containment of DM demands systemic changes at the societal level. This includes the implementation of robust public health policies aimed at enhancing healthcare accessibility, strengthening primary care infrastructure, and integrating patient-centered approaches into clinical practice. Public education campaigns to promote awareness, early detection, and preventive strategies are equally essential. Health-promoting environments—characterized by supportive urban planning, food security, and accessible exercise facilities—must be prioritized to facilitate healthier choices and reduce the burden of non-communicable diseases such as DM.

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