



REVIEW ARTICLE

Pancreatic islet transplantation as an alternative treatment for diabetes mellitus

Trasplante de islotes pancreáticos como tratamiento alternativo de la diabetes mellitus

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ABSTRACT

Introduction: Diabetes mellitus (DM) is a chronic endocrine-metabolic syndrome characterized by sustained hyperglycemia. Its global prevalence has increased significantly, necessitating the exploration of curative treatments beyond conventional glycemic control.

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Objective: To describe the current status of allogeneic pancreatic islet transplantation (AITT) as an alternative treatment for diabetes mellitus, with emphasis on its principles, applications, and limitations.

Methods: A narrative literature review was conducted between April and July 2024, consulting databases such as PubMed, SciELO, and Dialnet. Original articles, reviews, and case reports in Spanish or English, published primarily between 2020 and 2024, were included.

Development: AITT is emerging as a minimally invasive alternative to whole pancreas transplantation. It consists of the infusion of isolated islets into the hepatic portal circulation, aiming to restore endogenous insulin production. It is effective in a subgroup of patients with type 1 diabetes who experience severe, undetected hypoglycemia, achieving insulin independence or a significant reduction in insulin requirements in many cases. However, its widespread application is limited by the need for chronic immunosuppression, the progressive loss of graft viability, and, critically, the shortage of donors.

Conclusions: TAIP represents a niche and evolving therapeutic option for complex type 1 diabetes. Advances in bioengineering, cell encapsulation, and alternative sources (such as stem cells) aim to overcome its current limitations, although clinical validation is required for broader application.

Keywords: Diabetes mellitus; Pancreatic islets; Treatment; Transplant

RESUMEN

Introducción: La diabetes mellitus (DM) es un síndrome endocrino-metabólico crónico caracterizado por hiperglucemia sostenida. Su prevalencia global ha aumentado significativamente, lo que exige explorar tratamientos curativos más allá del control glucémico convencional.

Objetivo: Describir el estado actual del trasplante alogénico de islotes pancreáticos (TAIP) como tratamiento alternativo para la diabetes mellitus, con énfasis en sus fundamentos, aplicaciones y limitaciones.

Métodos: Se realizó una revisión narrativa de la literatura entre abril y julio de 2024, consultando bases de datos como PubMed, SciELO y Dialnet. Se incluyeron artículos originales, revisiones y reportes de caso en español o inglés, publicados principalmente entre 2020-2024.



Desarrollo: El TAIP emerge como una alternativa mínimamente invasiva al trasplante de páncreas completo. Consiste en la infusión de islotes aislados en la circulación portal hepática, buscando restaurar la producción endógena de insulina. Es efectivo en un subgrupo de pacientes con DM1 que presentan hipoglucemias graves inadvertidas, logrando en muchos casos independencia de insulina o reducción significativa de su requerimiento. Sin embargo, su aplicación a gran escala se ve limitada por la necesidad de inmunosupresión crónica, la pérdida progresiva de la viabilidad del injerto y, críticamente, la escasez de donantes.

Conclusiones: El TAIP representa una opción terapéutica de nicho y en evolución para la DM1 compleja. Los avances en bioingeniería, encapsulación celular y fuentes alternativas (como células madre) apuntan a superar sus limitaciones actuales, aunque requieren validación clínica para una aplicación más amplia.

Palabras clave: Diabetes mellitus; Islotes pancreáticos; Tratamiento; Trasplante

INTRODUCTION

Diabetes mellitus (DM) is a chronic endocrine-metabolic syndrome characterized by sustained hyperglycemia, resulting from a deficiency in insulin secretion, resistance to its peripheral action, or a combination of both mechanisms. Based on its etiopathogenesis, it is primarily classified into type 1 DM (T1DM), an autoimmune disease mediated by the selective destruction of insulin-producing pancreatic beta cells, and type 2 DM (T2DM), more prevalent in adults and associated with risk factors such as obesity, sedentary lifestyle, and insulin resistance ⁽¹⁾. Conventional management of both variants, based on exogenous insulin replacement (in T1DM) and insulin-sensitizing drugs (in T2DM), aims to control glucose levels but does not address the underlying cause of cellular dysfunction ⁽²⁾.

The pancreatic islets, or islets of Langerhans, represent the functional endocrine units of the pancreas. These microstructures, composed of specific cell populations (beta, alpha, delta, PP, and epsilon cells), are responsible for the coordinated production and release of key hormones for glucose homeostasis, such as insulin and glucagon. In type 1 diabetes (T1D), the irreversible loss of beta cells within the islets is the central pathogenic event leading to lifelong dependence on exogenous insulin. ⁽¹⁾

Since the first clinical descriptions of the disease in antiquity, the treatment of diabetes has evolved significantly. A fundamental milestone was the first pancreas transplant performed in 1966, which demonstrated the feasibility of restoring endocrine function through organ replacement.⁽³⁾ However, whole solid pancreas transplantation is a highly complex surgical procedure with associated morbidity and is limited by a shortage of donors. Data from international registries, such as the Scientific Registry of Transplant Recipients (SRTR), reflect a historical increase in the number of these procedures, although in the last decade a trend toward stabilization or decline has been observed, driving the search for less invasive alternatives⁽⁴⁾.

It is in this context that allogeneic pancreatic islet transplantation (AITT) emerges as a disruptive therapeutic strategy. Unlike whole organ transplantation, AITT involves the isolation and purification of islets from a donor pancreas for subsequent infusion into the recipient, generally via the portal venous system to the liver. This minimally invasive approach aims to specifically restore beta-cell function, correcting the primary pathophysiological defect of type 1 diabetes without the burden of major abdominal surgery⁽⁵⁾.

Globally, and particularly in the Cuban context, pancreatic islet transplantation (PAIT) represents a line of research and clinical application of great interest, especially for patients with type 1 diabetes who experience severe, undetected hypoglycemia despite intensive insulin management^(5,6). However, its large-scale implementation faces considerable challenges, such as the need for chronic immunosuppression to prevent rejection, the limited long-term viability of grafts, and, critically, the shortage of organ donors, which is exacerbated by the fact that multiple donors are required to treat a single recipient⁽⁷⁾.

The central scientific problem limiting the clinical impact of PAIT lies in the current inability to achieve a functional, durable, and immunosuppression-free replacement of pancreatic beta cells. This problem manifests itself in three interrelated dimensions: dysfunction and progressive loss of transplanted islets in a non-physiological hepatic microenvironment under immunological attack; the absence of unlimited and universally compatible cell sources that overcome the barrier of donor scarcity; and the lack of effective strategies to protect the graft from immune rejection without resorting to chronic systemic immunosuppression and its adverse effects.

Therefore, this review aims to describe the current status of pancreatic islet transplantation as an alternative treatment for diabetes mellitus, with an

emphasis on the scientific solutions being explored to address the aforementioned limitations. It will analyze its biological basis, clinical indications, isolation and implantation techniques, efficacy and safety outcomes, main limitations, and future prospects offered by fields such as tissue bioengineering and stem cell therapy.

MATERIALS AND METHODS

A narrative literature review was conducted between April and July 2024. The search strategy was designed to identify the most relevant and current evidence on pancreatic islet transplantation in the treatment of diabetes mellitus.

The literature search was performed in the PubMed, SciELO, and Dialnet databases. It was supplemented with searches in the academic repositories ResearchGate and MedlinePlus. Search terms were defined using the Health Sciences Descriptors (DeCS) thesaurus and its English equivalent (MeSH), combined using the Boolean operators AND and OR. The main keywords were: diabetes mellitus, pancreatic islets, islet transplantation, treatment, and transplant.

Inclusion criteria: Original articles, systematic reviews, meta-analyses, and case reports. Published between January 2020 and July 2024, to prioritize the most recent evidence. Seminal articles published before this period were exceptionally included if their relevance to the topic was fundamental. Publication language: Spanish or English. Open access to the full text or accessibility through the Cuban Health Telematics Network (INFOMED) was required. Content specifically addressing the clinical, technical, outcome, or future perspective aspects of pancreatic islet transplantation was considered.

Exclusion criteria: Articles for which the full text was not available. Editorials, letters to the editor, and conference abstracts not published as full articles. Studies dealing exclusively with solid pancreas transplantation without a relevant component on islets.

From the initial search, 25 articles were identified that met the eligibility criteria. More than 75 % of the final references belong to the period 2020–2024, ensuring the currency of the review. The information extracted from the selected sources was organized and synthesized narratively around the following thematic axes to structure the development of the article: biological foundations, clinical indications, procedure techniques (isolation and implantation), efficacy and safety results, complications, current limitations,

and future perspectives derived from research in bioengineering and cell therapy.

DEVELOPMENT

Biological Foundations and Justification for Islet Transplantation

The pancreatic islets, or islets of Langerhans, constitute the endocrine functional unit of the pancreas, organized into specialized microstructures that house cell populations with specific functions. Beta cells, which are the most abundant, are responsible for the synthesis and secretion of insulin in response to hyperglycemia, the hormone that lowers blood glucose levels ⁽⁶⁾. Alpha cells produce glucagon, a counterregulatory hormone that raises blood glucose by stimulating the release of glucose stored in the liver ⁽⁷⁾. Delta cells secrete somatostatin, a hormone that paracrine regulates the secretion of insulin and glucagon to maintain hormonal balance. PP (pancreatic polypeptide) cells produce pancreatic polypeptide, which is involved in the exocrine function of the pancreas and digestion. Finally, the less common epsilon cells synthesize ghrelin, a hormone that influences appetite and energy metabolism ⁽⁸⁾.

Type 1 diabetes mellitus (T1DM) is defined as an autoimmune disease characterized by the selective and progressive destruction of pancreatic beta cells by the immune system, leading to an absolute deficiency of endogenous insulin ⁽⁹⁾. Unlike other forms of diabetes, T1DM can manifest at any age, although it is more common in children and young adults. This primary pathophysiological defect is the fundamental target of islet transplantation. In contrast, type 2 diabetes mellitus (T2DM) is the most prevalent form and usually manifests in adults, although its incidence in young people has increased significantly due to factors such as obesity and sedentary lifestyles. In this condition, the body develops insulin resistance and, progressively, may exhibit insufficient production of this hormone ⁽¹⁰⁾. Conventional therapeutic management includes lifestyle modifications, oral medications, and, in advanced stages, insulin therapy. Although transplantation is not a standard treatment for T2DM, it is explored in selected cases of severe C-peptide deficiency and complex insulin dependence.

Whole Pancreas Transplantation: Evolution, Modalities, and Comparative Context

Historically, whole (or solid) pancreas transplantation has been the primary surgical option for restoring endocrine function in selected patients.

Simultaneous pancreas-kidney (SPK) transplantation is the most common type of pancreas transplantation, frequently recommended for patients with severe diabetes and advanced chronic kidney disease, especially when the glomerular filtration rate (eGFR) is less than 20 ml/min/1.73 m² ^(8, 9). In this procedure, both organs are usually obtained from a single deceased donor, although living donor protocols for kidney transplantation also exist. The indications for pancreas transplantation vary according to each center's protocols, although in most cases the primary criterion remains type 1 diabetes mellitus. In recent years, its use has expanded to selected patients with type 2 diabetes, as well as to individuals with chronic pancreatitis and neoplasms requiring total pancreatic resection.

On the other hand, isolated pancreas transplantation (IPT) is indicated in patients with preserved or mildly impaired renal function who experience severe complications of diabetes, such as unaware hypoglycemia, extreme blood glucose fluctuations, and a significant decline in quality of life. According to the United Network for Organ Sharing (UNOS) criteria, there are two candidate profiles for IPT: 1) patients with absolute endogenous insulin deficiency (C-peptide <2 ng/mL) requiring insulin therapy; and 2) patients with C-peptide >2 ng/mL but with a BMI <28 kg/m² who remain insulin-dependent ^(10, 11).

Limitations of whole pancreas transplantation and the emergence of whole pancreas transplantation (WPT)

Despite advances, whole pancreas transplantation involves major, highly complex surgery with significant perioperative morbidity and requires lifelong systemic immunosuppression, which limits its applicability ⁽¹²⁾. The standard technique involves the use of a whole organ from a deceased donor or, in selected cases, a pancreatic segment from a living donor via hemipancreatectomy ^(13, 14). The surgical procedure consists of preparing the graft (whole pancreas with a duodenal segment), positioning it in the pelvis, and vascularizing it via arterial anastomosis to the iliac artery and systemic or portal venous drainage ^(15, 16). Exocrine secretions are managed through duodenovesical or enteric diversion. These technical complexities, along with the shortage of donors, have driven the development of less invasive alternatives.

Allogeneic pancreatic islet transplantation (AITT): procedure, technique, and advantages

AITT is emerging as a less invasive therapeutic alternative to total pancreas transplantation. This technique involves a careful process of enzymatic digestion and mechanical separation of the donor's pancreatic tissue to obtain small cell clusters containing functional islets. Meticulous control of autodigestion is essential to avoid damaging viable endocrine tissue. The final product after isolation has a volume of less than 10 ml and a purity between 30 % and 90 %, although only about 1 % of the original islets are suitable for transplantation ^(15, 16).

The most commonly used implantation site is the liver. The procedure is performed via a catheter placed in the intrahepatic portal vein, which can be positioned through recanalization of the umbilical vein, cannulation of a tributary of the superior or inferior mesenteric veins, or by percutaneous puncture of the liver ^(17, 18). In the latter case, after identifying the portal vein and its branches via ultrasonography, a puncture is made with a 21-gauge Chiba needle, and a 4 French catheter is introduced into the portal vein using the Seldinger technique under intermittent fluoroscopic guidance. Before starting the infusion, a portogram must be obtained to confirm the catheter position ⁽¹⁹⁾. The cell infusion must be performed slowly to control portal vein pressure, with prophylaxis for portal thrombosis including sodium heparin ⁽²⁰⁾.

Results, Complications, and Current Limitations of IAT

The success criteria for IAT are defined by insulin independence or a significant reduction in its requirements, along with glycemic stabilization and the elimination of episodes of severe hypoglycemia unawareness ⁽²¹⁾. Studies indicate that many patients experience a significant improvement in glycemic control and a reduction in the need for exogenous insulin, although the survival rate of transplanted islets decreases over time ⁽²²⁾.

Despite its minimally invasive nature, islet transplantation is not without complications. The most frequent include alterations in liver function tests, hemorrhages, hemoperitoneum, and the formation of intrahepatic hematomas ^(23, 26, 30). These potential procedural complications, such as bleeding from the liver puncture site, portal thrombosis, and increased intraportal pressure, although infrequent, require specialized management.

However, the major limitations are systemic: the need for chronic immunosuppression to prevent rejection (associated with nephrotoxicity, increased risk of infections, and neoplasms), the critical shortage of donors (2-3 donor pancreases are required for a single recipient), and the progressive loss of graft viability in the hepatic microenvironment ^(24, 25, 27). These

restrictions have limited its application primarily to cases of recurrent severe hypoglycemia that do not respond to conventional treatment.

Technological Advances and Future Perspectives

The field of islet transplantation is experiencing notable technological development. The authors identify three main lines of research:

Immunoprotection Strategies: Microencapsulation systems in three-dimensional matrices allow for the creation of more physiological microenvironments for transplanted islets, protecting them from immune attack while allowing the exchange of nutrients and insulin ^(28, 29). These microcontainer systems have proven particularly effective in experimental models.

Alternative Cell Sources: The differentiation of pluripotent stem cells (iPSCs and ESCs) into functional pancreatic beta cells is being investigated using protocols that employ growth factors and specialized culture conditions ⁽³⁰⁻³²⁾. Concurrently, mesenchymal stem cells (MSCs) show potential to improve graft survival through paracrine mechanisms ^(33, 34). CRISPR/Cas9 technology allows for gene modification to optimize differentiation or create "invisible" cells to the immune system ⁽³⁵⁾.

Bioengineering and Microenvironment Improvement: Three-dimensional scaffolds and smart biomaterials with integrated growth factors are being developed to promote vascularization and reduce the immune response ^(36, 37). The combined use of accessory cells (endothelial, hepatic, pancreatic) favors neovascularization and improves graft viability ^(38, 39).

In the authors' consideration, pancreatic islet transplantation presents itself as a promising therapeutic option for patients with DM who experience severe complications and fail to achieve adequate glucose control through conventional treatments. Indications for both consecutive islet transplantation and autotransplantation can mitigate postoperative diabetes in specific cases ⁽⁴⁰⁾. Nonetheless, islet transplantation following kidney transplantation remains a subject of controversy, requiring an individualized assessment of risks and benefits.

Advances in cell therapy and immunomodulation, supported by numerous studies ⁽²⁸⁻⁴⁰⁾, point towards a future where islet transplantation could expand its indications and improve its long-term outcomes. However, the authors emphasize that all these innovative approaches remain in the experimental



phase, requiring rigorous validation before clinical translation. The synergy between bioengineering, immunology, and cell therapy represents the most promising frontier for turning IAT into an accessible, durable, and immunosuppression-free therapy for a broader spectrum of patients with diabetes.

CONCLUSIONS

Allogeneic islet transplantation is an effective treatment for a specific subgroup of patients with T1D and severe hypoglycemia unawareness, achieving insulin independence in a significant percentage in the short to medium term. Its main limitations are the dependence on chronic immunosuppression (with its adverse effects), the progressive loss of graft function, and the critical shortage of donors. Research is focused on alternative cell sources (stem cells, xenotransplantation) and bioengineering strategies (encapsulation) to overcome these barriers, although these alternatives remain in the preclinical or experimental phase. Currently, islet transplantation represents a niche, yet evolving, therapeutic option within the arsenal for managing complex type 1 diabetes.

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CONFLICT OF INTEREST DECLARATION

No conflicts of interest exist.

AUTHORSHIP DECLARATION

ABJ: Conceptualization. Investigation. Formal analysis. Methodology. Writing, review, and editing.

JMPG: Formal analysis. Investigation. Methodology. Drafting of the original manuscript and review/editing. Project administration and supervision.



BLSG: Formal analysis. Investigation. Methodology. Drafting of the original manuscript and review/editing. Project administration and supervision.

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