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Autologous Nonmyeloablative Hematopoietic Stem Cell Transplantation in New-Onset Type 1 Diabetes: A Multicenter Analysis

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Type 1 diabetes (T1D) is one of the major autoimmune diseases affecting children and young adults worldwide. To date, the different immunotherapies tested have achieved insulin independence in <5% of treated individuals. Recently, a novel hematopoietic stem cell (HSC)-based strategy has been tested in individuals with new-onset T1D. The aim of this study was to determine the effects of autologous nonmyeloablative HSC transplantation in 65 individuals with new-onset T1D who were enrolled in two Chinese centers and one Polish center, pooled, and followed up for 48 months. A total of 59% of individuals with T1D achieved insulin independence within the first 6 months after receiving conditioning immunosuppression therapy (with antithymocyte globulin and cyclophosphamide) and a single infusion of autologous HSCs, and 32% remained insulin independent at the last time point of their follow-up. All treated subjects showed a decrease in HbA_{1c} levels and an increase in C-peptide levels compared with pretreatment. Despite a complete immune system recovery (i.e., leukocyte count) after treatment, 52% of treated individuals experienced adverse effects. Our study suggests the following: 1) that remission of T1D is possible by combining HSC transplantation and immunosuppression; 2) that

autologous nonmyeloablative HSC transplantation represents an effective treatment for selected individuals with T1D; and 3) that safer HSC-based therapeutic options are required.

The incidence of type 1 diabetes (T1D) has been significantly increasing worldwide in the last decade, thus becoming the most common autoimmune disorder in children (1). T1D is characterized by a selective and aggressive destruction of insulin-producing β -cells orchestrated by autoreactive T cells (2,3). Unfortunately, exogenous insulin therapy does not always achieve the necessary metabolic control (4), nor does it prevent the occurrence of disease-associated degenerative macrovascular and microvascular complications (5) or halt β -cell decline (6).

The concept of the use of immunotherapeutic strategy to cure T1D has emerged from hallmark data generated using the NOD mouse model and has allowed for a better understanding of the pathogenesis of T1D (7). Several clinical trials—designed based on the preclinical successful targeting of components of innate and adaptive immune responses—performed thus far have failed to cure

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