



Association Between the Secretary Unit of Islet Transplant Objects Index and Satisfaction With Insulin Therapy Among Insulin-Dependent Islet Recipients

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ABSTRACT

Introduction. When patients do not become insulin independent after islet cell transplantation (ICT), another aim is to eliminate severe hypoglycemia. Previously we reported that a secretary unit of islet transplant objects (SUITO) index score >10 was associated with a reduction of severe hypoglycemia. In this study, we assessed patients' satisfaction with their insulin therapy based on the SUITO index.

Methods. The study involved 11 islet recipients with type 1 diabetes who underwent ICT but still used insulin. From those patients, 41 Insulin Therapy Satisfaction Questionnaires (ITSQ) were collected. The SUITO index (fasting C-peptide [ng/mL] \times 1500/blood glucose [mg/dL] $-$ 63) was calculated at the same outpatient visits that the survey was administered. ITSQ scores were summarized using subscales and compared among 3 groups: the pre-ICT group, the low-SUITO group (SUITO index score <10 post-ICT), and the high-SUITO group (SUITO index score ≥ 10). Higher survey scores indicated better satisfaction.

Results. Significant trend relationships across the 3 groups were observed in the ITSQ total score ($P = .02$ with Jonckheere-Terpstra test) and subscale scores of glycemic control ($P < .001$), hypoglycemic control ($P = .01$), and inconvenience of regimen ($P = .004$). The pairwise comparisons between the 3 groups found significant differences: high SUITO versus both pre-ICT and low SUITO for the total ITSQ score ($P = .03$ and $.005$, respectively) and glycemic control score ($P = .008$ and $.001$, respectively), and high SUITO versus low SUITO for hypoglycemic control score ($P = .04$) and inconvenience of regimen score ($P = .008$).

Conclusion. Islet recipients with a SUITO index ≥ 10 experienced higher satisfaction with insulin injection therapy compared with the pre-ICT group, even though they were insulin dependent. A SUITO index ≥ 10 is a reasonable benchmark for successful ICT.

ISLET CELL transplantation (ICT) is a promising treatment for the cure of type 1 diabetes.¹⁻³ The insulin independence rate after ICT has improved with the use of T-cell depletion for immunosuppression induction compared with the Edmonton protocol, and the current rate of approximately 50% at 5 years posttransplantation is close to that of whole-organ pancreas alone transplantation.^{4,5} However, approximately half the islet recipients have to resume insulin therapy posttransplantation, even using the new immunosuppression protocol. Of note, the main purpose of ICT is to improve patients' quality of life (QoL), so insulin independence is not always the final goal. Therefore, clinical management to retain better QoL in islet recipients

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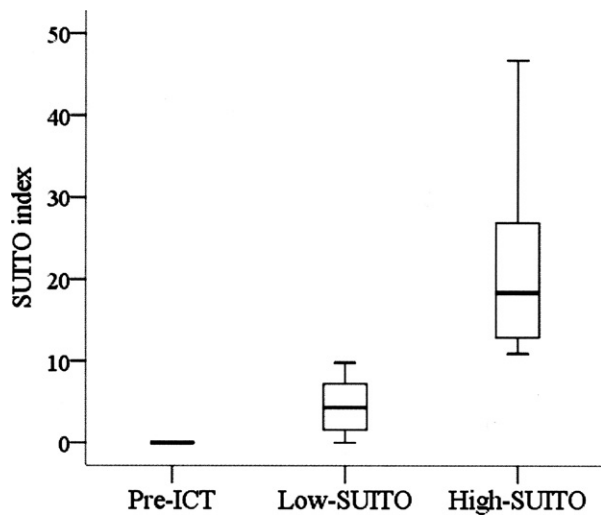


Fig 1. Distribution of the SUITO index in the pre-ICT group, the low-SUITO group (<10), and the high-SUITO group (≥10).

is a practical goal even if patients resume insulin therapy,⁶⁻⁹ and a simple clinical index to reflect both islet graft function and patients' QoL could be helpful for ICT clinicians.¹⁰⁻¹²

The secretory unit of islet transplant objects (SUITO) index was developed to assess islet graft function using a simple formula with blood test results for fasting C-peptide and glucose levels.¹³ A higher SUITO index has been associated with reduction of required exogenous insulin, fewer hypoglycemic events, better glucose tolerance, and better QoL in islet recipients.¹⁴⁻¹⁹ In the series of previous articles, 2 representative cut-off values of the SUITO index were demonstrated: a SUITO index score ≥26 predicted insulin dependence,¹³ and a SUITO index score ≥10 predicted prevention of severe hypoglycemic episodes.¹⁶ Herein, we hypothesized that the SUITO index was also associated with satisfaction with insulin therapy for insulin-dependent islet recipients and that the patients would achieve better satisfaction when the SUITO index score was >10. The aim of this study was to show the relationship between graft functional indices and satisfaction with insulin therapy in insulin-dependent islet recipients.

METHODS

Patients and Ethics

A total of 11 type 1 diabetic patients who underwent ICT at our hospitals (Baylor University Medical Center at Dallas and Baylor All Saints Medical Center at Fort Worth) but used insulin therapy were included in this study. Islets were prepared as previously described, except for the initial 8 transplantation using islets that were isolated at a remote center.²⁰⁻²³ The protocol in this study was approved by the institutional review board at Baylor Research Institute (Dallas, Tex, United States). All patients provided informed consent.

Insulin Therapy Satisfaction Survey

The subjects completed the Insulin Therapy Satisfaction Questionnaire (ITSQ) before ICT and 3,6,12,18, and 24 months after ICT when undergoing insulin therapy.²⁴ A total of 41 questionnaires were collected. The ITSQ, which was developed to assess the QoL of diabetic patients regarding their satisfaction with insulin therapy, is well validated.²⁵⁻²⁸ It consists of 22 questions in 5 subscales: inconvenience of regimen, lifestyle flexibility, hypoglycemic control, glycemic control, and insulin delivery device satisfaction. The answers were scored and summarized using subscales as originally described.²⁴

Metabolic Outcomes and Calculation of Clinical Graft-Function Indices

At monthly outpatient clinic visits, patients had blood tests to measure fasting C-peptide, blood glucose, and hemoglobin A1c (HbA1c) and reported insulin requirements and self-monitoring blood glucose (SMBG) data. In this study, blood test results within 1 week of the ITSQ survey were used as a representative value for each timepoint. The SUITO index was calculated by the following formula: fasting C-peptide (ng/mL) × 1500/fasting blood glucose (mg/dL) - 63.¹⁶ C-peptide glucose ratio and β score were also assessed as previously described: C-peptide glucose ratio = C-peptide (ng/mL) × 100/glucose (mg/dL).^{29,30} The M value as an ideal blood glucose level of 100 mg/dL and the mean amplitude of glycemic excursions (MAGE) were computed based on the SMBG records.³¹⁻³⁴ Relative insulin dose (%) was defined as daily insulin requirements (unit/d) at evaluation timepoint × 100/those at pre-ICT.¹⁴

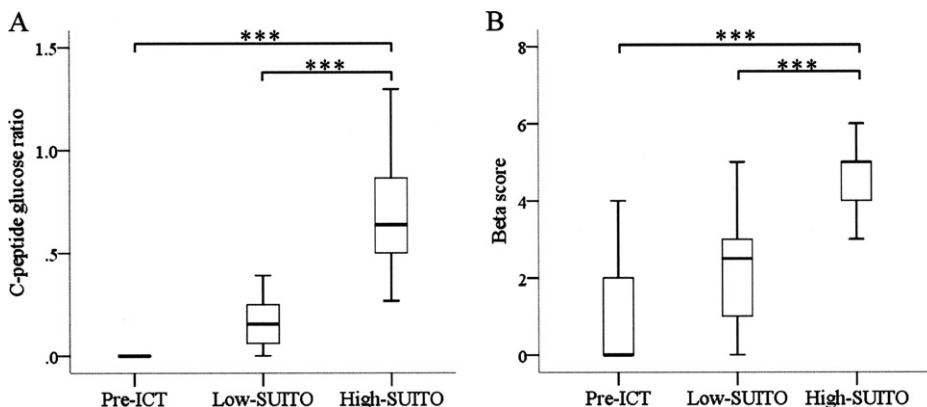


Fig 2. Graft function in the pre-ICT group, the low-SUITO group (<10), and the high-SUITO group (≥10), as indicated by the (A) C-peptide glucose ratio and (B) β score. ***P < .001.

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