IPITA 2021 VIRTUAL CONGRESS ABSTRACTS

307.5: Modified Approach Allowed for Improved Islet Allotransplantation Into Pre-vascularized Sernova Cell PouchTM Device - Preliminary Results of the Phase I/II Clinical Trial at University of Chicago

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Transplantation: December 2021 - Volume 105 - Issue 12S1 - p S25
doi: 10.1097/01.tp.0000804420.88438.67

Introduction: After the first-in-human pilot study which showed safety of the pre-vascularized Sernova Cell Pouch (SCP) in the subcutaneous space, we modified islet transplantation (ITx) conditions for improved engraftment in the SCP.

Methods: Two sets of the SCP were implanted in the abdominal anterior rectus sheath in seven patients with longstanding type 1 diabetes mellitus, problematic hypoglycemia and no stimulated C-peptide. Only highly purified islets were used for ITx and islets were suspended in the patient's own serum. Immunosuppression was initiated 1 month later followed by a marginal dose ITx after another month. Small sentinel SCPs were explanted for histopathological evaluation 3 months after each ITx.

Results: Seven patients were submitted to 21 study related surgeries with a wound infection in 2 patients after SCP implantation with only one patient requiring device excision. The first subject presented with persistent stimulated serum C-peptide at 6 months after 1st and 2nd ITx into SCP. After 2nd ITx, glucose control improved substantially including reaching optimal target values for CGM with only 5% of Time Below Range (TBR). Subsequent intraportal ITx allowed for insulin independence currently maintained for over 15 months. The second patient at 3 months after 2nd ITx had positive stimulated serum C-peptide (0.48 ng/mL) with reduction of HbA1c from 10.6% to 7.6%, decreased insulin requirement from 49 to 28 u/day, improved CGM with TBR <4%, and reduction in Time Above Range (TAR) from 76% to 48%. To date, stimulated C-peptide has been detected for over 9 months. Three additional patients recently received ITx and await evaluation.

Conclusion: Persistent islet graft function with sustained blood levels of C-peptide, reduction of HbA1c, improved CGM parameters, reduction of SHEs, and decreased total daily insulin requirement was achieved in the first 2 patients after ITx into SCPs implanted into abdominal wall. Significantly improved islet engraftment and clinical outcomes occurred using a modified approach for ITx into SCP.

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