

OPTN Pancreas Transplantation Committee

Meeting Summary

September 16, 2020

Conference Call

Silke Niederhaus, MD, Chair
Rachel Forbes, MD, Vice Chair

Introduction

The Pancreas Transplantation Committee (the Committee) met via Citrix GoToMeeting teleconference on 9/16/2020 to discuss the following agenda items:

1. Islet Wait Time Transfer Request
2. Discussion: Graft Failure Data
3. Project Update: Continuous Distribution
4. Additional Updates/Reminders

The following is a summary of the Committee's discussions.

1. Islet Wait Time Transfer Request

The Committee reviewed the process of reviewing Islet Wait Time Transfer Requests and discussed their first wait time transfer request since June 2015.

Process

- When a transfer request is received, it needs to be reviewed by the full Committee
- If the Committee approves of the transfer, the information will then be referred to the Organ Center
- Then, the request and the Committee's decision will be reported to the Board of Directors

Current Wait Time Transfer Request

- Patient was listed in 2017 for islet cells
- Currently, the patient's program does not perform islet transplants
 - Program would like to list candidate for pancreas alone
 - Transfer islet wait time to pancreas alone listing

Summary of discussion:

A member stated that, if a patient applies for islet transplantation, they likely have issues with hypoglycemia and they should be allowed to receive a pancreas transplant. Another member mentioned that if a patient is hypoglycemic, it's understandable that they want to get islets, but they should also be listed for a pancreas as well. Centers that do islet transplants should try to list candidates for both, which could be the reason why these Wait Time Transfer Requests are so infrequent.

A member mentioned that listing patients for both islet and pancreas transplants could be difficult for centers that only have an islet transplant program, and not a pancreas transplant program.

Another member mentioned that patients with severe hypoglycemic unawareness and Type 1 diabetes who come to islet transplant centers are informed about pancreas transplant and it's suggested they

consider it along with an islet transplant. However, these patients are usually only interested in islets at the time of listing for islets rather than surgery.

A member expressed concern that these patients would have an advantage over those patients who are already on the pancreas wait list.

Another member countered by mentioning that if a patient is presented two equivalent options (islet transplant which doesn't require surgery and pancreas transplant which does) most patients would opt for the option that doesn't require surgery. From this perspective, the patient would be transferring their time to a similar, equivalent form of therapy.

A member inquired if islet transplants are experimental. Another member explained that this is correct, depending on where you are in the U.S. Islets are only done as part of a clinical trial due to an FDA regulation, and is currently being challenged from different perspectives.

A member inquired why the Wait Time Transfer Requests need to be reviewed by the full Committee if they are so infrequent and if a small policy change could make these requests automatic. Members agreed that, while the review of Islet Wait Time Transfer Requests remain infrequent, it would be beneficial to make this process automatic. However, when these requests become more frequent with the expansion of the islet transplantation field, the transfer of wait time should be the candidate's islet wait time multiplied by some factor, in order to adjust the candidate's relative waiting time to what other pancreas candidates have waited for.

A member inquired if there has been a situation where a patient gets an islet cell and it fails early or is declared failure so they try to get wait time back for a pancreas from their islet time. Members explained that from a pancreas perspective, centers allow for a primary failure in either the first two weeks or 30 days if it's a technical failure and the patient gets their wait time back, but they were not sure what happened for islet primary failure.

All members were in favor of approving this Wait Time Transfer Request.

2. Discussion: Graft Failure Data

The Committee reviewed their past project, which changed the definition of pancreas graft failure, and discussed whether the new definition should be revisited.

In February 2018 the OPTN Board approved policy went into effect clarifying definitions for when a pancreas graft has failed.

Pancreas graft failure occurs when any of the following occurs:

- A recipient's transplanted pancreas is removed
- A recipient re-registers for a pancreas
- A recipient registers for an islet transplant after receiving a pancreas transplant
- A recipient's total insulin use is greater than or equal to 0.5 units/kg/day for a consecutive 90 days
- A recipient dies

Data summary:

- Pancreas graft survival was lower in KP recipients post policy
 - Likely due to changes in definition of graft failure
 - Not a true decline in pancreas graft survival
- Issues with required data elements reported via Status field and clinical values not reported
- Issues with pancreas graft failure definition threshold

- 1 or more missing data elements make it unable to calculate
- Recipient weight no longer on follow up forms - important data element to collect and should be placed back on these forms

Summary of discussion:

A member inquired about how many pancreas graft failures have been reported in the one year monitoring report. United Network for Organ Sharing (UNOS) staff stated that there have been four reported pancreas graft failures.

A member inquired about the total number of reports that were submitted. A member noted that it would depend on what the Committee is considering a report. It could be the report after the transplant or follow up reports. The first follow up report isn't due until 12 months after the initial transplant.

One member mentioned that some of these graft failures may have occurred already, but won't be reported until the one year follow up form and other failures may not occur until after the one year follow up.

A member inquired about the total number of pancreas transplants that had been completed in the one year monitoring report. UNOS staff stated that 153 pancreas transplants had been completed. A member expressed concern at this low number – based on the average of about 800 pancreas transplants per year, there should be about 1,000 pancreas transplants completed in this 1.5 year time period.

A member inquired about when the next graft failure report is due. UNOS staff stated that the plan is to present the next report during the Committee's spring meeting.

A member suggested reviewing whether forms have been accurately submitted or not and any missing data points. A member noted the following key questions to better understand if the Committee needs to further discuss the definition and data collection surrounding failed or partially functioning pancreas grafts:

- How many transplants have been done since this graft failure definition has been implemented?
- How many of them have reported one year outcomes?
- How many have been declared failed or partially functioning?
- How many are declared functioning?

A member noted that it might be difficult for centers to gather data on recipients' insulin dosage for the annual report, since they may only see the recipient once a year or once every other year. A member suggested looking at the first three years of pancreas transplant follow up to see if that change in definition has increased the reported graft failure.

A member mentioned a discussion at the Scientific Registry of Transplant Recipients (SRTR) Consensus Conference regarding missing data. The consensus was that SRTR should substitute missing data with values that are least valuable to the center, thus encouraging centers to accurately record data, and should consider including timeliness and completeness of the data submission as a quality indicator. A member stated that, with how this was implemented, it may have only applied to risk-adjusted missing variables and not to pancreas graft failure missing variables, but this could still be worth consideration if there's a high rate of missing data on pancreas follow up reports.

A member pointed out that, currently, graft failure is not reported as a measure of outcome for Centers for Medicare and Medicaid Services (CMS) or for the Membership and Professional Standards Committee (MPSC). Meaning a graft failure report isn't something MPSC will flag the center for and the graft failure isn't reported on the online form. Members noted that this was correct; however, it was

due to a lack of uniform definition for graft failure and the collection of meaningful data. The current reporting form has been adapted to fit the new definition of pancreas graft failure, but graft failure hasn't been reported since there hasn't been a full year of follow up yet.

A member inquired if there's any way to look at what the reporting form looks like as it currently exists at the next Committee meeting. UNOS staff agreed to show the reporting form at the next Committee meeting.

The Committee Chair summarized the following two issues the Committee has with pancreas graft failure:

- The graft failure definition will need to be re-evaluated as there are still arbitrary cut offs
- The removal of the weight data element on the follow up form is critical to the definition of insulin use per body weight and should be added back
 - This question is still indirectly in the follow up form if the recipient is on insulin – must provide the total insulin dosage per day as expressed in units per kilogram per day

Next Steps:

UNOS staff should investigate what happened to the weight variable – was it an oversight that weight was removed from the follow up form? And if so, what can be done to reinstate the variable?

Members agreed that if the weight variable can be added back to the follow up form with little to no effort, then the Committee should postpone re-evaluating the pancreas graft failure definition until they have statistically meaningful data.

3. Project Update: Continuous Distribution

The Committee was updated on the progress of the Kidney Pancreas Continuous Distribution Workgroup.

- First workgroup meeting held on 9/11
- Discussion
 - Review of CD Project
 - Review and discussion of Attributes
- Proposed project approach
 - Discuss attributes applicable to each organ (kidney and pancreas) separately
 - Highlight attributes that require input/expertise of both Committees

Summary of discussion:

The Committee Chair proposed presenting the attributes slides from the first Continuous Distribution meeting to the Pancreas Continuous Distribution Workgroup.

4. Additional Updates/Reminders

The Committee was provided the following updates and reminders:

- Public Comment is open until 10/1/2020
 - Members can review proposals and provide their individual input on the OPTN public comment site
- Please complete Lung Committee Continuous Distribution prioritization exercise
 - Closes on 10/1/2020
- Next Pancreas Continuous Distribution Workgroup meeting – 9/25/2020

Upcoming Meetings

- October 9, 2020 (Virtual In-Person Meeting)
- November 18, 2020 (teleconference)

Attendance

- **Committee Members**
 - Silke Niederhaus
 - Antonio Di Carlo
 - Ken Bodziak
 - Maria Helena Friday
 - Parul Patel
 - Piotr Witkowski
 - Pradeep Vaitla
 - Raja Kandaswamy
 - Randeep Kashyap
 - Tarek Alhamad
 - Todd Pesavento
- **HRSA Representatives**
 - Marilyn Levi
- **SRTR Staff**
 - Bryn Thompson
 - Jon Miller
 - Nick Salkowski
- **UNOS Staff**
 - Amber Wilk
 - Joann White
 - Kerrie Masten
 - Matthew Prentice
 - Nang Thu Thu Kyaw
- **Other Attendees**