OPTN Vascularized Composite Allograft Committee
Meeting Summary
December 1, 2021
Conference Call

Bohdan Pomahac, MD, Chair
Sandra Amaral, MD, MHS, Vice-Chair

Introduction

The Vascularized Composite Allograft Committee (the Committee) met via Citrix GoToMeeting teleconference on 12/01/2021 to discuss the following agenda items:

1. Proposal: *Establish Membership Requirements for Uterus Transplant Programs*
2. Proposal: *Modify Graft Failure Definition for VCA*

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

1. Proposal: *Establish Membership Requirements for Uterus Transplant Programs*

This proposal would establish membership requirements for uterus transplant programs, including requirements for uterus living donor components. There is a proposed amendment submitted by an OPTN Board of Directors (Board) member to modify the living donor uterus surgeon requirements.

Bylaw summary:

The current proposal reads:

The demonstrated experience of the uterus recovery surgeon must include one of the following, performed as primary surgeon or co-surgeon, within the last five years:

- At least 2 living donor uterus recoveries or
- 1 living donor uterus recovery, at least 1 deceased donor uterus procurement, and at least 1 direct observation of living donor uterus recovery, or
- At least 2 deceased donor uterus procurements and at least 2 direct observations of living donor uterus recoveries

The proposed amendment would change this language to:

The demonstrated experience of the uterus recovery surgeon must include one of the following, performed as primary surgeon or co-surgeon, within the last five years:

- At least 2 living donor uterus recoveries or
- 1 living donor uterus recovery, at least 1 deceased donor uterus procurement, and at least 1 direct observation of living donor uterus recovery, or
- At least 2 deceased donor uterus procurements and either
    - At least 2 direct observations of living donor uterus recoveries, or
    - At least 10 radical hysterectomies performed as either primary or co-surgeon

Summary of discussion:

The main topic of discussion was the proposed amendment to the living donor uterus surgeon requirements. Concerns were raised by a Board member that the requirements were too restrictive and

would inhibit the development of the field in such an early stage. The proposed amendment would include a pathway in addition to the revised Committee pathways which would allow living donor uterus surgeons to perform only radical hysterectomies and deceased donor procurements in order to meet the requirements.

The Chair noted that this would allow a living donor uterus surgeon to meet the requirements to perform living donor recoveries while eliminating the need to perform or observe living donor recovery. The first question posed to the Committee was why living donors led the field in the U.S? Members noted that there was a supply issue, insofar as, there was significant interest from living donors to participate in these programs and living donors are preferred. With living donors, the ability to do tests and check the donor's history is much easier. Furthermore, in the original trials for uterus transplant, living altruistic donors were used, and deceased donors were incorporated afterwards, reversing the traditional pathway of organ donation.

A VCA Committee member spoke to the unique considerations that differentiated radical hysterectomy procedures from living donor procedures. They also said that the rate of grade III or IV complications within living donors is approximately 10%, which is a safety concern; in addition, the field has reached a point where there is enough data to demonstrate that the risks in this procedure are separate from those of a radical hysterectomy. The member emphasized this is especially true for an elective procedure. Finally, they noted that, in adding deceased donor procurement as a pathway for surgeons, given the infrequency of deceased donation, this will not allow significantly more access to the field.

A second member supported this analysis, stating that they believed the complication rate could be even higher. At this point in the field, they remarked, it is still a learning curve and the community needs to be very careful.

The Chair inquired as to the differences between living and deceased donor procedures. A member explained that, with deceased donor procurement, a surgeon can recover an extensive amount of soft tissue as there is no concern given to donor injury. When performing the same operation on a living donor, surgeons cannot go as lateral when recovering vasculature. Even when performing a radical hysterectomy, the concern is primarily about the preservation of the tissues surrounding the uterus, rather than the preservation of the uterus itself. The ureter, the member noted, is much less of an issue when simply removing the uterus rather than removing it with the intent of transplant.

The Chair also asked for input from the OPTN Living Donor Committee (LDC) and an attendee, a living uterus donor. The donor noted that, knowing their surgeon had performed a number of these procedures before them definitely influenced their decision. When asked if, hypothetically, they knew they were the surgeon's first time performing this procedure, whether they would have more hesitation, they noted that they "would feel more comfortable knowing [their] doctor had done this before" and "[they] definitely would have way more hesitation". The Chair of the LDC, noted they were also a living liver donor, and, from both perspectives, want "living donor experience or a bare minimum observation on my surgical team [prioritized]" as opposed to logistical challenges. The Vice-Chair of the LDC voiced support for the Committee's opposition, stating that they had previously been undecided, but upon hearing Committee members' perspectives, as well as the unique challenges posed by living donation versus deceased donation, they did not support the amendment.

Staff provided a brief interjection to clarify that these requirements were only impacting programs that performed living uterus donor recoveries, and that uterus transplant programs would not be required to have a living donor component.

A member offered one summary of points to the Committee. They stated that the field of living donor uterus transplant is at a vulnerable point, as it makes the jump from a research endeavor to becoming

standard of care. With the amendment, the proposal with the revision would be too forward-reaching, especially when considering the notion that a living donor program could undertake an operation they have never seen before. They felt that the programs performing living donor uterus procedures understood the safety concerns inherent to the operation due to significant experience as a research endeavor, and opening the program up with the proposed requirements could present donor safety possibilities.

Staff noted that the primary objection to the current proposal was that it was too limiting with respect to the number of procedures currently being performed, and requiring this much consideration to safety would bar programs from even attempting to institute a program.

A second member rebutted, stating that the current proposal is only setting these requirements for programs seeking to perform living uterus donation and will not impact programs performing only deceased. They feared that more mistakes would be made if the OPTN began approving programs without experience and risking shutting the field down if they experience severe complications.

The LDC Chair added that they intended to write a brief statement of support for the Committee's position opposing the proposed amendment, adding that they did not support the proposed amendment.

Next steps:

The Committee will consider the feedback given from the LDC and living uterus donor in attendance.

2. Proposal: *Modify Graft Failure Definition for VCA*

This proposal will update the current definition of graft failure for VCA to include for the possibility of planned removal within VCA. It is slated to go out for public comment during the Winter 2022 cycle.

Summary of discussion:

Staff noted that there was a minor clerical change to the proposal which would add a date field to the Transplant Recipient Follow-Up (TRF) and Transplant Recipient Registration (TRR) forms for the date of planned removal for a VCA graft. This would require a vote of support from the Committee to include this change. Staff also noted this was in-line with how other organs are tracked for failure on TRRs and TRFs.

The Committee unanimously approved the addition of a date field to the Uterus TRR and TRF (14 yes, 0 abstain, 0 no)

Next steps:

Staff will follow up with UNOS IT staff to alert them of the change.

Upcoming Meeting

- January 12, 2022

Attendance

- **Committee Members**
  - Bohdan Pomahac
  - Sandra Amaral
  - Brian Berthiaume
  - Lori Ewoldt
  - Stevan Gonzalez
  - Vijay Gorantla
  - Darla Granger
  - Amanda Gruendell
  - Liza Johannesson
  - Deborah McRann
  - Paige Porrett
  - Deborah Priebe
  - Patrick Smith
  - Mark Wakefield
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
- **UNOS Staff**
  - Kristine Althaus
  - Isaac Hager
  - Lindsay Larkin
  - Krissy Laurie
  - Meghan McDermott
  - Tina Rhoades
  - Leah Slife
- **Other Attendees**
  - Jen Gobrecht
  - Elias Nahel
  - Nikki Wehmeir
  - Heather Hunt