OPTN Heart Subcommittee
Meeting Minutes
October 24, 2019
Conference Call

Shelley Hall, MD, Subcommittee Chair

Introduction

The Heart Subcommittee met via Citrix GoTo teleconference on 10/24/2019 to discuss the following agenda items:

1. Adult Heart Exception Project: Discuss guidance opportunities addressing the use of Exceptions to assign candidates to Status 2 under the Intra-aortic Balloon Pump (IABP) criteria

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

1. Adult Heart Exception Project: Discuss guidance opportunities addressing the use of Exceptions to assign candidates to Status 2 under the Intra-aortic Balloon Pump (IABP) criteria

UNOS staff gave a brief summary of the 10/17 meeting and the decisions made. The Subcommittee proceeded to identify information needed for submitting an exception request and the potential outreach methods and types of information to include in a guidance document.

Summary:

During the discussion, the Chair stated that a challenge encountered from creating past heart policies was that the intent of the Subcommittee was not always reflected in the policies developed. Because of this lack of clarity in policy, in order to combat the increase use of IABPs over VADs, the Subcommittee had previously decided to create a guidance document outlining appropriate reasons for extending or submitting an exception. It was acknowledged that though there are other heart criteria's that need to be addressed, right now the priority is on the increased use of IABPs.

In terms of creating a guidance document for acceptable VAD contraindications when asking for an IABP exception, many members had agreed that this would be helpful. One member commented that there is contention in the community about "personal preference" for VADs and IABP. This member also commented that there hasn't been any new OPTN data analysis on the post-October 2018 policy changes. This was concerning for some members, because outside data analyses (not OPTN) in some ISHLT data abstracts are not showing favorable results, and showing a significant increase in IABPs. To note these ISHLT abstract are not public right now, and therefore the Subcommittee does not know exactly what is being stated or analyzed in them. There is also reportedly discussion in the community about the overuse of IABPs. However, Subcommittee members acknowledged that a guidance document might be the fastest method for correcting behavior.

The Subcommittee discussed the contraindications to VAD that would be included in a guidance document, including: contraindications to oral anticoagulants, infections, inotropes, right heart failure, small left ventricle, surgical complications and thrombotic risks. Another discussion revolved around reasons that a candidate may not need a VAD. One member supported addressing hemodynamic criteria for initial exception requests for IABP, and that the center should provide actual reasons for cardiogenic shock (such as worsening organ function). The Subcommittee began by looking at the

current policy criteria for status 2 IABP and agreed that not meeting these criteria for specific reasons would be appropriate for an exception (e.g. systolic blood pressure less than 90). The Chair stated that not meeting the systolic blood pressure requirements, or not including the values was a common issue when reviewing exception and extension narratives. Other examples included data showing worsening organ function, though this can be difficult to put guidelines around. Because of these difficulties, members supported having a broader definition of "worsening organ function", and suggesting centers use more specific data that is evidence-based. One member voiced caution for writing a document that makes it seem that not meeting certain criteria or provind certain information would disqualify a center from submitting an exception case. This member supported the RRB's making the ultimate decision when approving or denying cases. Another member commented that it would be helpful for centers to include in exception narratives other therapies that have not worked, methodologies, and documenting any changes with inotropes or vasopressors. There was discussion on "methodologies" and whether certain methodologies should be judged as better than others by RRBs. Members supported having narratives include "methodologies", but that they shouldn't ask for RRBs to weigh them against each other. In terms of the wedge being less than 15 and needing an IABP, one member commented that septic shock could be acceptable an acceptable reason. Subcommittee members agreed that they do not need to include too many specific reasons, such as septic shock, in the guidance document. The Subcommittee briefly reviewed an exception narrative template that a member had developed.

Last, the Subcommittee reviewed a monthly email template used for the National Liver Review Board, and educating transplant cardiologists, transplant heart programs, and transplant surgeons via review cases. Most members supported sending out a monthly email notification to transplant centers and regional review boards. This educational, 1-page memo might include data about status 4 candidates being transplanted, the fact that the Subcommittee is reviewing cases, and the issue of IABPs. Other suggestions included sending a brief email after each Subcommittee meeting, and making sure the communication is concise.

Next steps:

The Subcommittee will circulate a draft version of the guidance document for feedback and review.

Upcoming Meeting

- December 12, 2019