OPTN Heart Transplantation Committee
IABP Subcommittee
Meeting Summary
May 04, 2023
Conference Call

Shelley Hall, MD, Chair

Introduction

The IABP Subcommittee, the Subcommittee, met via Citrix GoTo teleconference on 05/04/2023 to discuss the following agenda items:

1. Data Presentation
2. Time on VAD Discussion

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

1. Data Presentation

The Subcommittee submitted a data request that asked how many status 2 candidates with an Intra-Aortic Balloon Pump would not qualify under the proposed inotrope and hemodynamic requirements. Contractor Staff presented their findings to the Subcommittee.

Summary of Presentation:

The OPTN Contractor Staff reviewed all IABP candidates listed in status 2 from October 2018 to October 2021. In order to properly address the Subcommittee's question, staff analyzed the data in two different ways. First, staff examined the status 2 candidates who had qualified for status 3 based on inotropes. Using this method 16.8% of IABP candidates in status 2 would qualify under the new proposal, 83.2% would not qualify for status 2. The second method analyzed the data was by examining the number of status 2 IABP candidates who would qualify under the proposed policy using risk stratification. This method manually examined the inotropes used to treat the candidates prior to the placement of an IABP. Using this method staff was able to determine that 34.7% of candidates would still qualify, and 65.3% would not qualify under the proposed policy change. Staff noted that the seven-day time period was unable to be incorporated into this analysis.

Summary of discussion:

Two members expressed shock at the high rate of IABP use without reporting inotrope use. The Chair explained that many people have realized that the hemodynamics are the same for IABP and inotropes but IABP qualifies candidates for status 2, so they are skipping inotropes and going straight to IABP.

The Chair stated they are receiving very positive early feedback on this proposal because people in the heart community understand there is a problem and this is a reasonable way to address it.

A member asked if anyone is worried about what the response to this could be, after seeing the data it is clear this will be a big change. The Chair responded that the hope is people will understand that status 2 has increased in size, and the policy will hopefully level out all the statuses. The member responded the policy is directly addressing status 2 but it will have an impact on multiple statuses in the way the Chair described.

A member responded that the data reflects what people have suspected is happening in practice, that people who are not sick enough for IABP or inotropes are receiving an IABP prematurely because they will qualify for status 2. The member continued that the data is not surprising but should be eye opening when presented in public comment.

The Chair pointed out that some centers may not be reporting their inotrope use or hemodynamic measurements because they do not have to provide that information in order to qualify for status 2. By mandating the reporting of these factors it will become more clear how many physicians are attempting medicines prior to IABP, but also how many are not.

A member stated their hope that this will encourage more people to use ventricular assistance devices (VAD) because there is a misconception that candidates on VAD are not receiving transplants. The Chair responded in agreement but also noted that it seems difficult for candidates on VAD to be transplanted because everyone is listing their patients in status 2 making it difficult to allocate to other candidates.

2. Time on VAD Discussion

The Chair led the subcommittee in a discussion regarding VADs.

Summary of Presentation:

The Chair reminded the Subcommittee that VADs are currently not part of the status 2 policy they have been working on because the Subcommittee tried to keep the scope as narrow as possible. However, time on VAD has become an issue within the transplant community. The Subcommittee could begin discussing the VAD issue and then allow a different subcommittee to take over the work. The current goal is to present a time on VAD project to the OPTN Policy Oversight Committee in June 2023, send the project to public comment in January of 2024, and for the OPTN Board of Directors to vote on the policy in June of 2024.

Mortality and morbidity increase with time spent on VAD. The current suggested plan for time on VAD would place a candidate in status 4 for the first year on VAD, for their second year on VAD the candidate would move to status 3, and in year three the candidate would move to status 2 and remain there. All device complications listed within policy would remain in place.

Summary of discussion:

A member asked if the data this recommendation was based on analyzing a specific brand and model of VAD. The Chair responded that is was a collection of all continuous VADs.

A member asked, bioethically speaking, if a stable candidate on a VAD and a status 2 candidate should be in the same status. The Chair pointed out that this is a concept plan, and the plan the OPTN Heart Committee ends up adopting could be drastically different. Additionally, the data will dictate which status a candidate will move to and when. The Chair warned that this could mean the data shows the problem does not need to be addressed and members should be prepared for that possibility.

Staff asked the Subcommittee if the increased status based on time on VAD is similar to something already in existence or is it new and needs to be created. Staff elaborated and asked if any new data will need to be collected. The Chair responded that the date of implant of the VAD will need to be recorded. The Chair continued that one issue that will need to be worked out is what happens if there is a device malfunction that qualifies a candidate for status 3, but their time on VAD qualifies them for status 2; would the candidate default to the higher status or would some other solution need to be explored.

A member of the Subcommittee suggested that the solution should be similar to continuous distribution. Time on VAD is being considered for the medical urgency attribute and there would be a separate wait time attribute.

The Chair suggested that an easier solution to this may be keeping the candidate at whatever status they were originally listed at for the first year on VAD and then moving the candidate up a status each year they are on a VAD. This would mean there is a time element to the proposal and a status escalation component.

A member stated they do not believe there is a need to prove that there is a direct correlating justification between time on VAD and status, one of the bigger goals of this project is to give patients on VAD hope they will receive a transplant. The IABP proposal should help status 3 and status 4 candidates receive more allocation offers, which would help VAD candidates and a VAD proposal would increase their chances of receiving an organ offer.

Staff asked if this would require extension forms to move from one status to the next and could a candidate risk going back a status if the forms is not submitted. The Chair pointed out that since the policy deals with time there would be no way to take time back so the candidate could not move back in status. The candidate would remain at that status until they move to the next.

Staff asked if there was any data that needs to be requested. The Chair responded that there is quite a bit of data already in the monitoring report, some more granular data on VAD waitlist deaths would be helpful, but most of the data and information is available in publications from the past few years.

Upcoming Meetings

- May 11, 2023

Attendance

- **Subcommittee Members**
  - Shelley Hall
  - Richard Daly
  - Glen Kelley
  - Hannah Copeland
- **HRSA Representatives**
  - Marilyn Levi
- **SRTR Staff**
  - Katherine Audette
  - Yoon Son Ahn
- **UNOS Staff**
  - Alex Carmack
  - Alina Martinez
  - Eric Messick
  - Holly Sobczak
  - Kelsi Lindblad
  - Kim Uccellini
  - Sara Rose Wells