OPTN Heart Subcommittee
Meeting Minutes
September 26, 2019
Conference Call

Shelley Hall, MD, Subcommittee Chair

Introduction

The Heart Subcommittee met via Citrix GoTo teleconference on 09/26/2019 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

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:

The Heart Subcommittee Chair provided an overview of the initial review of exception request narratives. The Chair and Thoracic Committee Chair reviewed 225 exception request narratives associated with Status 2 submitted between June 1, 2019 and August 31, 2019. The narratives were provided by Research staff. The two reviewers worked independently. The Subcommittee Chair mentioned that the review may have benefitted from comparing their findings after an initial sample of 20, for instance, and that after reading the narratives they may have also chosen different groupings.

To start, the Subcommittee Chair and the Committee Chair identified five groupings for consideration: Reason for Exception; Diagnosis; VAD Denial Documented; RV Failure Noted, and Device Chosen When Applicable. The preliminary categories were created to put some objectivity around the effort. Within each of the give groupings, they created more listings. After completing their reviews, they compared how they had categorized the exception requests. Under the Reason for Exception grouping, they only agreed about 40% of the time on their decisions. Their choices were more aligned within the other groupings. For example, they agreed approximately 75% of the time for the VAD Denial Documented, 80% of the time for RV Failure Noted, 98% of the time for Device Chosen, and 68% of the time for Diagnosis.

After summarizing the review and results, the Subcommittee Chair said the next steps are for the members to determine what to do with the information. For instance, a large number of Status 2 exception requests have been submitted. They are not sure what percentage of the Status 2-related requests are approved by the regional review boards, but the percentage could be important. If 50% of candidates are assigned to Status 2 by exception that is probably a bigger problem than if only 5% of the candidates are in Status 2 by exception.

In terms of next steps, should the Subcommittee consider creating a guidance document that would be directed at the regional review board staff as well as the transplant programs? Moreover, should a

guidance document just be targeted at Status 2 exception requests involving Intra-aortic Balloon Pumps (IABP) criteria? The subcommittee Chair said this is the most common Status 2 exception requested. Should such a guidance document detailing how to apply for a Status 2 exception, as in what pertinent information should be in the narrative from the programs? What areas should the Subcommittee look to next in regards to the data for other paths forward? For instance, should they review exception requests again using different questions, or more granularity?

A Subcommittee member asked about the inter-variability of the review responses, and what the frequencies or volumes were of their responses. The Chair said they had not gotten that deep in the analysis. The member asked if those numbers were necessary to make decisions on the questions. Does the Subcommittee need to know the percentages that the two Chairs agreed that the reason was due to a lack of hemodynamics in the request, or due to the use of non-qualifying hemodynamic information? This would be a difficult request because their responses were different. The Thoracic Committee Chair said the challenge of the initial analysis was that their responses did not agree enough to make statements like 25% of the reasons for *x* factor.

The Thoracic Committee Chair suggested the benefit of the reviews to this point is that they now have a better understanding of the narratives being used. The Subcommittee Chair said they tried to perform the reviews in the same way regional review boards would.

There were some questions about what information was needed and how it addressed the subject of exception requests. For instance, don't they need to know the reasons the candidates were submitting exception requests, especially if it was tied to not being granted an extension to their previous listing? The way the exception requests work though is that the narrative provides all the information. It is then useful for the chairs to review the narratives because they can make the clinical decisions.

Based on the initial pass, the review suggested that most balloon pumps were for either non-qualifying hemodynamics or the hemodynamic information just wasn't included—which implies the candidate was not qualified. Recalling the reviews, a lack of blood pressure below 90 was probably the most common thing. However, if looking broadly at the balloon pump exception requests, they just did not meet the hemodynamics qualifications. It did not appear that exceptions were requested because the program thought the candidate had a contraindication to a VAD. Overall, it seemed like the candidates were not meeting the hemodynamics; although sometimes the programs just did not bother providing the information, but that may have been because the program did not think their candidate would qualify so the program did not think it was worth submitting the hemodynamics.

It was suggested that the IABP-related requests accounted for about 50% of the exception requests. The Subcommittee Chair said because of the high percentage, the IABPs were a good place to start in terms of developing a guidance document because such a document could have a large impact. On the other hand, it appeared that transplant programs are struggling with the definitions of VT, but VT is a small category.

In terms of reviewing and/or categorizing the requests, a place to start would be for the Subcommittee to identify the information they would want to see when reading an exception request for a balloon pump? What information should be required for a balloon pump candidate to be listed as a standard status 2?

It was also suggested that the Subcommittee should consider whether they should identify what constitutes a contraindication to a durable VAD is worthwhile, or is it whatever a program thinks is a contraindication for them, or makes a program think a balloon pump is a better option? One of the concerns is that probably for almost everyone if they can get a heart in the next week by staying on a balloon pump, then it is probably better to stay on the balloon pump. However, that was not what the

Thoracic Committee intended with the policy when it was created. The question was asked whether the Subcommittee members think there is guidance or some way to tell the regional review boards and transplant programs in terms of what justifies leaving a balloon pump in their candidate? For instance, if a candidate is on a balloon pump but there is RV failure on echo, does the Subcommittee think that circumstance should be better defined? Or, should the Subcommittee include specific criteria in a guidance document that states if the program does not want to put in a VAD because the candidate has a small LV cavity, then this is the size (*x* or *y*) below which it should be?

It was also mentioned that balloon pumps used before the change in allocation policy were predominantly for people who did not have VAD as an option. The data was highest risk candidates for balloon pump without a salvage. Now, it appears it is being used because it gets a candidate Status 2. So, the intent of the usage of balloon pumps has changed. As a result, there is a massive increase in balloon pump usage.

The Subcommittee could consider spending more time on analysis, meaning the balloon pumps get dropped to Status 3, or they can develop guidance in the interim for how to create narratives and how to document contraindications to VAD. In addition, does the Subcommittee feel that patient preference is a pertinent factor because that appeared in some of the exception narratives. A Subcommittee member brought up that during the Region 9 meeting in Buffalo, a participant at the Thoracic breakout session asked if patient preference could be used as a valid reason for the continued use of a balloon pump? The member said that the participant thought the patient preference stipulation had been written into policy. Another member replied that is definitely not in the policy. It may have been discussed by the Committee when the members were working on the new policy language but that did not get written into policy.

The Subcommittee chair said that if they are analyzing balloon pump usage, just letting the transplant programs know that usage is being reviewed by the Subcommittee will help with policy behavior. Subsequent to that, what does the Subcommittee feel is appropriate documentation for contraindications to VAD and on-going hemodynamic needs? Because during the review, they read narratives where balloon pumps had been used but did not help the candidates at all. A key to a guidance document being successful will be sorting out who really needs a Status 2 assignment.

The Subcommittee Chair asked the members if they agreed that the Status 2 exception requests for candidates on balloon pumps is a good place to start? A members agreed, and said it would be helpful for other Subcommittee members to review the narratives as well. The member wanted to know why the review had been limited to the two Chairs. It was discussed that during a previous review of VAD restrictions, the Chairs at the time had been the only ones who reviewed the narratives, so they followed the same approach to start this review. It was suggested that if additional reviews are required, the Subcommittee could consider sharing the narratives with additional members. The Subcommittee Chair recommended getting consensus on their next steps before going much farther down the road. If the Subcommittee members agree to look at balloon pumps first, then they need to decide how to look at them. Should they be a little more granular and have a clear checklist of what they Subcommittee is going to do as they review the exception requests? Then maybe they can determine who else might need to review them.

There was an extended discussion about what the differences are between exceptions and extensions. The Subcommittee members reviewed Policy 6.1.B.v: Intra-Aortic Balloon Pump (IABP), particularly the extension language included in the section. There were questions about why exceptions don't automatically follow not being able to extend a candidate? Another member wanted to know if members are using patient preference as a contraindication because that would be a problem. A

concern was expressed that for analysis purposes the Subcommittee needs to review the extension requests that may have preceded an exception request.

Another member asked what instructions have already been provided to the regional review boards to help guide their decisions? The answer was 'none.' There hasn't been any assistance beyond the orientation video that was created.

The Subcommittee decided to identify some of the conditions that need documentation as part of an exception request. These included: Missing hemodynamics; Non-qualifying hemodynamics; Presence of inotropes (yes or no); Reasons for no inotropes; VT; Angina, or Unknown/Not mentioned.

The Subcommittee Chair said that a guidance document will need to document that the spirit of policy is that higher statuses represent progressive acuity and failure of other therapies.

Next steps:

The Subcommittee will meet on October 17th for the full Thoracic Committee meeting, and continue its work on defining the basic information needed for inclusion in an exception form.

Upcoming Meetings

- October 17, 2019 In-person meeting
- October 24, 2019 Teleconference
- December 12, 2019 Teleconference