OPTN Liver and Intestinal Organ Transplantation Committee
Hepatocellular Carcinoma (HCC) Stratification Subcommittee
Meeting Summary
October 28, 2024
Conference Call

Chris Sonnenday, MD, Chair

Introduction

The OPTN Hepatocellular Carcinoma Subcommittee (the Subcommittee) met via WebEx teleconference on 10/28/2024 to discuss the following agenda items:

1. Background
2. Review Hepatocellular Carcinoma (HCC) Stratification Models

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

1. Background

Summary of Presentation

The Subcommittee's guiding principles are as follows:

- Current priority in liver allocation for HCC candidates has been relatively optimized.
- Allocation priority for HCC candidates should be benchmarked relative to Median Meld at Transplant (MMaT).
- Not seeking to change HCC criteria

Previously the Subcommittee discussed the following:

- Identifying a population of HCC transplant candidates needing lower priority based on favorable biology and low drop out risk.
- Including a waiting time elevator to address community concerns about assigning certain candidates lower priority
- That an HCC stratification score should include MELD 3.0
- A subset of candidates within Milan criteria has worse post-transplant outcomes and the difficulty of addressing this without changing OPTN policy.

Topics for discussion include the following:

- Models other than MELD, specifically OPOM
- How to identify candidates based on favorable or unfavorable biology, drop out scores, and post-transplant survival
- Decompensated HCC patients with low MELD who are unable to receive liver-directed therapy.
- Patients with tumor location that limits effectiveness of liver-directed therapy.
- Additional data request or modeling needed for HCC stratification recommendation.

Summary of discussion:

No decisions were made regarding this agenda item.

The Subcommittee discussed patients with low MELD scores whose priority is not well represented by their MELD score. They noted that it is difficult to include Child-Pugh scores and conditions like ascites into a stratification model because there is inherent subjectivity in them. One member commented that including the MELD score in the chosen HCC stratification model would help these patients but that the Subcommittee should continue to explore other ideas to help these patients. One Subcommittee member mentioned that relying on the review board may be appropriate as they can modify patient priority on a case-to-case basis.

Next steps:

The Subcommittee will continue to discuss these issues.

2. Review HHC Stratification Models

Summary of Presentation

One option for HCC stratification is the Multi-HCC Score model. This model stratifies HCC patients into quartiles by dropout risk and awards higher priority to those patients. The model uses an elevator method to give more priority to patients over a 12-month period. The advantage of using this model is that it uses currently available data, can be updated every three months, and has similar post-transplant survival rates among all quartiles.

Another option for HCC stratification is the HALT-HCC Score. This model uses currently available listing data to calculate a tumor burden score (TBS) using the Pythagorean theorem. This model could be updated every three months, stratifies patients for dropout risk and post-transplant survival, but has not been validated with MELD 3.0 and acuity circles data.

Summary of discussion:

No decisions were made regarding this agenda item.

The Subcommittee discussed the possibility of a patient's score being downgraded under the Multi-HCC Score model due to successful treatments other than transplant. One member noted that a patient with multi-focal disease could be well treated, ready for transplant and then go from MMaT-3 to MMaT-5 which would be problematic. The Subcommittee agreed that they did not want to downgrade patients priority scores, and the suggestion was made that the language around this stratification model be updated to ensure patients priority scores cannot go down.

The Subcommittee discussed the timeframe in which the Multi-HCC Score Model updated patient's priority scores. The current model uses 0 months, 6 months, and 12 months to update patient priority scores. The Subcommittee entertained the possibility of changing those times to every 90 days to match the required 90-day update. The Subcommittee felt that 3 months was too short of a period and that the liver transplant community preferred the 6-month mark. The Subcommittee felt that adding a 9-month mark would complicate the model without adding benefit.

The Subcommittee discussed the fact that the HALT-HCC model includes post-transplant survival which is not something considered for non-HCC patients nor is it considered in the upcoming switch to continuous distribution. The Subcommittee also discussed the fact that calculating the TBS could be burdensome for the community and that while it could be automated, that would require programing

work to make it happen. The Subcommittee felt the model was viable but that compared to the Multi-HCC model, it was more complicated.

The Subcommittee discussed how the upper quartile of patients in the HALT-HCC model has two distinct types of patients grouped together, some with a high chance of recurrence of HCC and some with a much lower chance. The Subcommittee discussed how most transplant centers have their own rules for handling possible recurrence after transplant and if the Subcommittee should leave that in the hands of the center by using a different model.

The Subcommittee discussed if they should look at other models that use OPOM rather than MELD. One member noted that the Liver Committee went with MELD in continuous distribution because there did not appear to be much difference between MELD and OPOM for liver transplant but that might not hold true within the HCC subpopulation. Another member said the data was not available to tell and that it would be difficult to get, as OPOM does a lot of opaque calculations. The Subcommittee also noted that using OPOM would require a lot of education for the transplant community, and this was one of the reasons it was not selected for use in the first iteration of continuous distribution. Another member noted this could be a way to experiment with OPOM on a smaller scale. The Subcommittee felt that OPOM would generate unique priority scores for HCC patients which feels overly complicated and would stratify HCC patients to a degree that is unnecessary.

The Subcommittee discussed running some simulations with past data using the Multi-HCC model. Some members commented that transplant behavior has changed and that many HCC patients are no longer waiting six months due to numerous factors like machine profusion. The Subcommittee also discussed checking to identify any potential subset of HCC patients that this model might miss or poorly capture.

Next steps:

The next steps are to test the Multi-HCC model, make adjustments to the model so patients do not lose priority, and develop a more formal recommendation for the Liver Committee.

Upcoming Meetings

- November 21, 2024 @ 3:30 PM ET (teleconference)

Attendance

- **Subcommittee Members**
  - Chris Sonnenday
  - Scott Biggins
  - Shimul Shah
  - Allison Kwong
  - Neil Shah
  - Joseph DiNorcia

- **HRSA Representatives**
  - Jim Bowman

- **SRTR Staff**
  - Katie Audette

- **UNOS Staff**
  - Emily Ward
  - Cole Fox
  - Jesse Howell
  - Ben Schumacher
  - Laura Schmitt
  - Joel Newman

- **Other Attendees**
  - Neil Mehta
  - Parissa Tabrizian