OPTN Liver and Intestinal Organ Transplantation Committee
National Liver Review Board (NLRB) Subcommittee
Meeting Summary
April 13, 2023
Conference Call

James Trotter, MD, Chair

Introduction

The OPTN National Liver Review Board Subcommittee (the Subcommittee) met via Citrix GoToMeeting teleconference on 04/13/2023 to discuss the following agenda items:

1. Revisions to Hepatocellular Carcinoma (HCC) Guidance
2. Intra-hepatic Cholangiocarcinoma

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

1. Revisions to Hepatocellular Carcinoma (HCC) Guidance

The Subcommittee reviewed revisions to HCC guidance.

Summary of discussion:

In June 2022, NLRB guidance was simplified for candidates who had HCC that was treated and then recurs. In March 2023, a potential inconsistency between new guidance for HCC candidates who recur and existing guidance was noticed. Diagnostic criteria are different in subsequent sections of the guidance document. One section outlines guidance for candidates with cirrhosis and HCC beyond T2 but within generally accepted criteria for downstaging who underwent complete resection with negative margins and developed T1 or T2 recurrence, states that the recurrent T1 HCC must be biopsy proven and the recurrent T2 HCC must be proven via LI-RADS 5. This differs from the prior section of the guidance document, which allows either biopsy or LI-RADS 5 to be used to diagnose either recurrent T1 or T2 HCC.

A member noted that this inconsistency was likely an oversight, and supported modifying the guidance document to correct the inconsistency. The member added that LI-RADS 5 should be accurate. The Chair agreed.

Another member noted that there should be no biologic differences in how recurrences for HCC and downstaging are treated. The member added support for aligning the language to provide clarification.

The Subcommittee agreed to address the inconsistency in guidance.

The Chair suggested for the Subcommittee to continue to engage with LI-RADS subject matter experts to ensure language continues to be up to date.

Next steps:

The Subcommittee will move forward with clarifying the guidance document.

2. Intra-hepatic Cholangiocarcinoma

The Subcommittee reviewed literature on intra-hepatic cholangiocarcinoma (ICC) and discussed creating potential NLRB guidance.[1,2,3,4,5]

Summary of discussion:

The Chair asked how ICC is different than hilar cholangiocarcinoma. A member responded that it is based on location.

A member clarified that the proposed guidance would address small unresectable ICC.

Another member noted small ICC tumors are generally discovered incidentally during liver transplant workup or post-operatively. The member noted that data observes these patients to have relatively good outcomes.

Another member expressed interest in unresectable noncirrhotic ICC because transplant oncology is a growing field. The member suggested expanding the proposed project idea to incorporate this population as well. The member stated that a score recommendation of MELD 15 may be appropriate for this population.

Another member asked for the population size. A member noted that the population size may be small now, but that may be due to these candidates receiving low calculated MELD scores. The member stated that the numbers may increase if there is the pathway to access an increased MELD score through exceptions.

Another member stated that patients with ICC should not be treated different than HCC patients if the outcomes are similar.

A member asked what the diagnostic criteria is for ICC. Another member noted that biopsy proven ICC should be a necessary criteria. The member explained that biopsy proven is important to understand that the tumor is ICC and not HCC, or mixed HCC and ICC. A member asked if mixed tumors should be included.

A member spoke with colleagues ahead of the meeting and noted that there was support for the proposed project idea. The member stated that there is good evidence on ICC tumors less than two centimeters, but not three centimeters.

A member suggested a lower score recommendation than median MELD at transplant (MMaT) minus three. The member stated the community may be more supportive of a lower score recommendation, and it also may encourage use of marginal livers.

Another member proposed creating guidance for both smaller and larger ICC in order to create a more comprehensive guidance document for the NLRB. A member supported this idea.

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[1] Sapisochin, G., et al. (2014). "Very early" intrahepatic cholangiocarcinoma in cirrhotic patients: should liver transplantation be reconsidered in these patients?. *American journal of transplantation : official journal of the American Society of Transplantation and the American Society of Transplant Surgeons*, *14*(3), 660–667. https://doi.org/10.1111/ajt.12591

[2] Hong, J. C., et al. (2011). Comparative analysis of resection and liver transplantation for intrahepatic and hilar cholangiocarcinoma: a 24-year experience in a single center. *Archives of surgery (Chicago, Ill. : 1960)*, *146*(6), 683–689. https://doi.org/10.1001/archsurg.2011.116

[3] Sapisochin, G., et al. (2016). Liver transplantation for "very early" intrahepatic cholangiocarcinoma: International retrospective study supporting a prospective assessment. *Hepatology (Baltimore, Md.)*, *64*(4), 1178–1188. https://doi.org/10.1002/hep.28744

[4] Ito T, et al. A 3-Decade, Single-Center Experience of Liver Transplantation for Cholangiocarcinoma: Impact of Era, Tumor Size, Location, and Neoadjuvant Therapy. Liver Transpl. 2022 Mar;28(3):386-396. doi: 10.1002/lt.26285. Epub 2021 Oct 21. PMID: 34482610.

[5] Ziogas, I. et al. (2021). Liver Transplantation for Intrahepatic Cholangiocarcinoma: A Meta-analysis and Meta-regression of Survival Rates. *Transplantation*, *105*(10), 2263–2271. https://doi.org/10.1097/TP.0000000000003539

Another member suggested including guidance for patients with colorectal liver metastases. A member supported this and suggested an exception score of MELD 15.

Another member noted support for creating guidance for the three different diagnoses. The member stated that creating a pathway for increased MELD scores via exceptions will help increase access to transplant and allow the transplant community to study these populations.

A member asked whether there are histological findings that are associated with worse survival. The member explained that exception points could be given based on more favorable histology or tumor biology. Another member responded that there are not differentiation for the smaller ICC tumors.

Next steps:

The Subcommittee will continue to discuss the project idea and refine the project scope.

Upcoming Meeting

- May 11, 2022 @ 2:30 PM ET (teleconference)

Attendance

- **Subcommittee Members**
  - Alan Gunderson
  - Allison Kwong
  - Greg McKenna
  - James Eason
  - Jim Pomposelli
  - Jim Trotter
  - Neil Shah
  - Shimul Shah
  - Sophoclis Alexopolous
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Representatives**
  - Katie Audette
- **UNOS Staff**
  - Erin Schnellinger
  - Katrina Gauntt
  - Laura Schmitt
  - Matt Cafarella
  - Meghan McDermott
  - Susan Tlusty