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MEETING REPORT

The 2024 ILTS-ILCA consensus recommendations for liver transplantation for HCC and intrahepatic cholangiocarcinoma

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Abstract

Liver transplantation (LT) provides the best long-term survival outcomes for patients with liver cancer. As a result, the field of transplant oncology has grown greatly over the past few decades, and many centers have expanded their criteria to allow increased access to LT for liver malignancies. Center-level guidelines and practices in transplant oncology significantly vary across the world, leading to debate regarding the best course of treatment for this patient population. An international consensus conference was convened by the International Liver Transplantation Society and the International Liver Cancer Association on February 1–2, 2024, in Valencia, Spain to establish a more universal consensus regarding LT for oncologic indications. The conference followed the Delphi process, followed by an external expert review. Consensus statements were accepted regarding patient assessment and waitlisting criteria, pretransplant treatment (including immunotherapy) and downstaging, living donor LT, post-LT patient management, and patient- and caregiver-related outcomes. The multidisciplinary participants in the consensus conference provided up-to-date recommendations regarding the selection and management of patients with liver cancer being considered for LT. Although participants deferred to center protocols in many cases, there was great interest in safely expanding access to LT for patients with larger tumor burden and biologically amenable lesions.

Keywords: consensus development conference, HCC, intrahepatic cholangiocarcinoma, liver transplantation, transplant oncology

INTRODUCTION

Liver transplantation (LT) for oncologic indications has been expanding and growing in frequency over the past few decades[1,2] in part due to superior outcomes over resection and newer available therapies.[3,4] Prevalence rates of primary liver cancers continue to increase,[5,6] specifically HCC and intrahepatic cholangiocarcinoma (iCCA), leading to a rise in the number of patients who may benefit from LT. Liver cancer was once thought to be an absolute contraindication to LT. However, with the advent of the Milan criteria, HCC became a widely accepted indication for LT.[7] As experience grew, centers reported good post-LT survival outcomes in patients with larger tumor burden, leading to extended criteria for LT.[8,9] Selection criteria also began to incorporate noninvasive biomarkers such as alpha-fetoprotein (AFP) to offer LT among those with a more favorable biology independent of tumor burden.[10,11] Similarly, LT was initially not offered to patients with iCCA, despite reports of success with LT for hilar cholangiocarcinoma.[12] Initial size-based selection criteria opened the door to LT for patients with iCCA,[13] followed by markers of biological aggressiveness.[14,15] However, despite improved OS compared to earlier experience, in some countries, iCCA is not granted any priority for LT. Notably, the US Organ Procurement and Transplantation Network

Abbreviations: AFP, alpha-fetoprotein; DCP, des-γ-carboxy prothrombin; DDLT, deceased donor liver transplantation; iCCA, intrahepatic cholangiocarcinoma; ILCA, International Liver Cancer Association; ILTS, International Liver Transplantation Society; LDLT, living donor liver transplantation; LI-RADS, Liver Imaging Reporting and Data System; LRT, locoregional therapy; LT, liver transplantation; mRECIST, Modified Response Evaluation Criteria in Solid Tumors; MVI, macrovascular invasion; OC, organizing committee; TACE, transarterial chemoembolization.

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National Liver Review Board updated its policies in June 2024 and will offer exception points to patients with a single unresectable iCCA lesion ≤ 3 cm in diameter in the background of cirrhosis that has been radiographically stable for at least 6 months following neoadjuvant chemotherapy or locoregional therapy (LRT).

Despite the widespread acceptance of LT for primary liver cancer, there is a great amount of variability in center practices. Heterogeneity in selection criteria exists not only across countries and continents but also between centers in a similar geographic location. These differences include different cutoffs for tumor burden and application of biomarkers. Centers may also have different protocols for pre-LT and post-LT patient management informed by clinician expertise and center experience. Given the variety of approaches to patient management, there is a need to summarize best practices for caring for patients with HCC or iCCA in the transplant setting based on evidence. Major advances in the treatment of primary liver cancer, such as the approval of new immunotherapy treatments, necessitate an updated list of recommendations specific to transplant oncology.

This manuscript describes the recommendations of the 2024 International Liver Transplantation Society (ILTS)-International Liver Cancer Association (ILCA) Joint Conference on LT for HCC and iCCA. The goal of this consensus conference was to provide an updated set of recommendations for multidisciplinary teams managing patients with HCC or iCCA who are being considered for LT, building off previous reports.[16,17]

METHODS

A joint international consensus conference of the ILTS and ILCA was held on February 1–2, 2024, in Valencia, Spain, to develop consensus guidelines regarding the role of LT for HCC and iCCA. The organizing committee (OC), comprised of members from both societies, identified key topics and created 7 working groups focused on addressing various aspects of LT. Working group members were selected by the OC based on their scientific and clinical expertise, including clinical outcomes, publication records, and expert status in the field. The OC composed a list of 4–6 questions for each working group to research and address in their recommendations.

The working groups were composed of 6–7 experts from medical and surgical specialties in transplant oncology. Working group members performed an extensive English-language literature search of medical publication databases (PubMed, Embase, and Scopus) to locate peer-reviewed publications addressing their group's topic. After performing the literature review, members met to discuss their findings and to formulate an evidence-based recommendation to answer each of the OC's questions relating to their assigned topic.

The conference itself followed the Delphi method.[18] Members of each working group formally presented the group's recommendations based on their findings from the literature reviews. After a period of discussion, conference participants voted on their support for each recommendation. To accept a recommendation, $\geq 80\%$ of the participants needed to agree with that version of the recommendation. When the 80% cutoff was not met, revisions to the recommendation were discussed at the conference and voted upon again until the 80% threshold was met.

A secondary review of the recommendations was made by an independent external jury of 8 experts in the field of transplant oncology. These reviewers were again selected based on similar criteria of academic and research excellence but had not attended the consensus conference and were not a part of any prior discussions or voting, thereby providing an unbiased review of the recommendation statements. Again, $\geq 80\%$ agreement was needed again to accept a specific recommendation. After the external panel review, 3 recommendations failed to pass the voting process because of the framing of the statements and were sent back to the respective working group leads for editing and clarification.

RESULTS

A total of 120 participants attended and took part in the consensus conference. Through the Delphi process, 54 recommendations were agreed upon (Table 1). More detailed discussions and results of each group's literature search are in the Supplemental Material, http://links.lww.com/LVT/A906.

Working group A: Assessment of candidates with HCC for liver transplantation

Patient selection for LT for HCC should include regular monitoring via imaging and noninvasive biomarkers. All patients with cirrhosis on the LT waitlist (WL), regardless of HCC status, should receive surveillance screenings consisting of ultrasound imaging and AFP quantification every 6 months. CT and MRI may also be utilized as needed, and they may provide superior visualization to ultrasound, particularly in those with a poor ultrasound visualization score (B/C), which is more common in males, obese patients, steatotic liver disease, and Child-Pugh B/C. ^{18}F-flurodeoxyglucose positron emission tomography may be less useful in this setting but does have value in select cases. Although the sensitivity of some imaging modalities may be

TABLE 1 Summary of recommendations made by the ILTS-ILCA consensus conference working groups

Question	Recommendation	Level of evidence	Strength of recommendation
Working Group A: Assessment of Candidates With HCC for Liver Transplantation			
What is the optimal screening modality and frequency for patients with cirrhosis on the transplant list? What is the utility and role of tumor markers?	We recommend semi-annual US + AFP as the primary surveillance modality for patients in whom adequate visualization is achieved by US. Patients with poor visualization may instead undergo liver-protocolized CT or MRI imaging.	Weak	Moderate
Is dynamic CT and or MRI enough to accurately diagnose the size and number of tumors?	Dynamic CT and MRI provide valuable diagnostic information for HCC, but their limitation in accuracy for determining the exact size and number of HCC lesions varies based on lesion size, imaging techniques, patient liver function, and the specific diagnostic criteria used and may underrepresent pathologic burden.	Moderate	Strong
What is the role of additional modalities like PET and CEUS? Are any of these modalities able to predict aggressiveness?	An FDG-PET may be useful to predict aggressiveness; however, its routine use based on the current evidence is not recommended.	Moderate	Strong
Should there be an age limit in well-compensated patients with cirrhosis and HCC for considering LT, given the increased risk of frailty and/or comorbidities?	We recommend that there should not be a different age limit (compared to patients without HCC) in well-compensated patients with cirrhosis and HCC considering liver transplantation.	Moderate	Strong
Is a 5-year survival benefit the correct "tool" to decide which patients to transplant?	Liver transplantation should be considered in patients who can achieve an expected 50% or greater 5-year overall survival.	Moderate	Strong
When is it too early to offer transplant, in the context of deceased donor (DDLT) and living donor liver transplantation (LDLT)?	Transplantation should not be offered to patients who have lesions that are not clearly HCC or to patients in whom resection or ablation therapy provides safe and adequate effective complete tumor removal with potential cure.	Moderate	Strong
What is the role of tumor biopsy in the era of next-generation sequencing? What is the role of circulating tumor DNA in this setting?	Biopsy is not needed in patients with characteristic HCC features on imaging given high positive predictive value. However, if any atypical imaging features are present, a biopsy should be performed to rule out cholangiocarcinoma (CCA) or mixed tumors, which can impact eligibility, prognosis, and optimal treatment.	Weak	Moderate
Should the criteria for resection vs. transplant be different in patients with HCC in the background of HBV or metabolic dysfunction–associated steatohepatitis (MASLD)?	Currently, there are no data to support a different approach in non-cirrhotic HBV-HCC patients or MASLD-HCC patients. Thus, there should not be different criteria for non-cirrhotic HCC/MASLD-HCC vs. other etiologies. CEUS is a validated tool in the diagnosis of HCC and useful in the characterization of nodules deemed indeterminate on CT/MRI.	Weak	Moderate
Working Group B: Criteria for Listing Patients With HCC			
Should liver transplantation be restricted to HCC patients who have a predicted 5-year survival comparable to non-HCC patients? Should OS be HCC-specific (eg, METROTICKET 2.0)?	Liver transplantation should not be restricted to HCC patients who have a predicted 5-year survival rate comparable to non-HCC patients. However, organ availability in different regions should be considered in allocation policies to avoid disadvantaging non-HCC patients.	Moderate	Moderate
Should size and number still be the main consideration for selecting patients for LT for HCC? Should AFP, AFP-L3, and DCP be criteria for listing/maintaining on WL? Can the expansion of criteria be done without downstaging? What are the best scoring systems to predict recurrence pre- and post-LT?	Criteria for listing patients with HCC for liver transplantation must not rely solely on tumor size and number and should consider biomarkers (mainly AFP) and their dynamics on the waitlist. Emerging data suggest the use of AFP-L3, DCP, and PET-CT can add prognostic value.	Moderate	Strong

Can the expansion of criteria be done without downstaging?	We recommend that patients beyond Milan criteria can be transplanted without downstaging if outcome measures are preserved. However, response to LRT can provide insight into the risk or recurrence of HCC and is recommended.	Moderate	Moderate
When is bridging needed and when is it not?	Bridging with LRT is recommended in patients with HCC to keep patients within transplant criteria when longer waiting times (>6 mo) are anticipated based on the available donor pool. Bridging is also recommended in patients with more aggressive tumor biology (eg, rapid interval growth, high AFP) as a response to LRT may identify high-risk patients less likely to benefit from LT.	Moderate	Strong
What is the most adequate bridging therapy?	Choice of LRT should be based on tumor size, location, institutional/transplant expertise, and expected response. There is limited evidence available to recommend one LRT modality over another, and published comparison studies have demonstrated similar post-LT outcomes.	Weak	Moderate
What is the frequency of imaging while waiting and what are the drop-out criteria?	Patients undergoing LRT as bridging therapy should be monitored with contrast-enhanced cross-sectional imaging (CT or MRI) at 1 and 3 mo after treatment and every 3 mo thereafter until transplanted or waitlist dropout. Criteria for drop-out should be those that exceed the local transplant criteria.	Moderate	Moderate
What are the best downstaging modalities or strategies?	Downstaging is recommended for patients who present beyond local criteria without extrahepatic disease and no portal vein macrovascular invasion to attain a sustained response based on imaging and biomarker criteria. Until more data are available, the recommended endpoint is transplantation for patients based on local criteria.	Weak	Moderate
Should there be an upper limit of downstaging or should all comers be included?	Select patients with tumor burden beyond local criteria have acceptable posttransplant survival; however, a subset of patients beyond local criteria are at a significantly higher risk of dropout and poor posttransplant outcomes, including those with worse liver function and high AFP (>1000). Caution should be exercised when considering further expanding liver transplantation to this group.	Moderate	Moderate
What constitutes a successful DS: Milan criteria, partial response, mRECIST, or RECIST?	Following LRT, mRECIST/LI-RADS-R is recommended for response assessment and determination of downstaging success.	Moderate	Moderate
Is response to treatment enough? Should partial response or complete response be the goal of downstaging?	While a complete radiographic response is not necessary to proceed to transplant, complete response (CR) is desirable as the burden of viable tumor on the explant is associated with posttransplant recurrence.	Moderate	Strong
How should progression be defined while on the waitlist or after downstaging?	Progression should be assessed with mRECIST or RECIST 1.1, and the criteria should be selected depending on the downstaging treatment utilized. AFP and other serum biomarkers (including AFP-L3%, DCP) can be used as adjuncts for response assessment in combination with cross-sectional imaging.	Moderate	Moderate
What is the optimal time after downstaging to wait before listing for LT?	A period of observation of at least 3 mo post-successful downstaging is recommended to allow for monitoring of biological stability before transplantation.	Weak	Moderate
If a patient decompensates before downstaging, should LT be performed based on calculated MELD?	Downstaging success should be explicitly defined before beginning a downstaging protocol, particularly in patients at higher risk of hepatic decompensation (Child-Pugh B/C) and those with tumors less likely to respond to LRT (increased size/number, high AFP). Immediate	Moderate	Moderate

TABLE 1. (*continued*)

Question	Recommendation	Level of evidence	Strength of recommendation
	transplantation in patients who are not successfully downstaged is associated with poor transplant outcomes and is not recommended.		
Should patients who received curative treatment (surgery, ablation) with no residual tumor but who are at high risk of recurrence be considered for transplantation?	Prophylactic or "ab initio" LT in patients at high risk of HCC recurrence can be considered in well-selected patients within centered-specific criteria. The length of observation after prophylactic liver transplantation should be established to examine the occult aggressiveness of the HCC resulting in recurrence after transplantation.	Weak	Moderate
Should patients who received curative treatment (surgery, ablation) with no residual tumor but who are at high risk of recurrence be considered for transplantation?	Salvage liver transplantation in patients with HCC recurrence or liver insufficiency can be as safe and effective as primary transplantation for HCC in patients that meet transplantation criteria.	Weak	Moderate
What are the best biomarkers for monitoring response to downstaging treatment?	AFP is the only biomarker that is established for use in clinical practice, and should be monitored before and after downstaging to determine downstaging success as well as drop-out and HCC recurrence risk. There are several promising serum-based and imaging-based biomarkers that may be useful to assess response to LRT; however, these require further study and validation before adoption into routine clinical practice.	Moderate	Strong
Should macrovascular invasion be a contraindication for LT? If not, what limitations should be placed regarding the degree of PVT, mandatory pre-LT waiting time after response, optimal neoadjuvant treatment?	Select patients with macrovascular invasion (Vp1 or vp2) may be considered for LT if able to be successfully downstaged to local criteria (based on radiographic response, decrease in serum AFP). A minimum observation time of 12 months post-DS may allow for assessment of tumor biology.	Weak	Weak
Do surgical considerations need to be different based on the specific type of LRT used in downstaging?	Pre-LT LRTs exhibit a low rate of complications after LT and, therefore, should not be avoided if clinically indicated.	Weak	Moderate
If a patient is not eligible for MELD exception points, what measures can be implemented to obtain an organ?	Extended criteria donors can be used for patients listed for HCC, particularly in the case of clinically compensated patients. Machine perfusion of extended criteria donors is recommended to improve graft viability.	Weak	Moderate
Working Group C: Immunotherapy and Liver Transplantation			
Who is a good candidate for immunotherapy pretransplant? Should it be considered for downstaging to LT?	In patients beyond transplant criteria, without extrahepatic disease who do not achieve sufficient response to LRT, immunotherapy might be used for downstaging, but clinical trials are needed.	Weak	Moderate
Should patients with macrovascular invasion be considered for transplant after response to immunotherapy?	There is currently no evidence to support the use of immune checkpoint inhibitors (ICIs) before transplant in the context of vascular invasion. Results from the ongoing clinical trials are awaited. On a case-by-case basis, patients may be referred to a transplant program for multidisciplinary tumor board evaluation.	Weak	Strong
Should there be a waiting period after response to ensure no recurrence off immunotherapy?	The panel was unable to make a specific recommendation given lack of scientific evidence available. Prospective clinical studies should evaluate the minimum interval required to consider liver transplantation without risk of recurrence in patients who have been successfully downstaged to transplant criteria.	Weak	Weak

Is there an immunotherapy regimen that is less risky and does this differ according to class of agent (eg, anti-PD-(L)1 +/- anti-CTLA-)?	Despite the differences in ICI mechanisms of action, there is not enough data to support the safety of one ICI over the other.	Weak	Moderate
What should be the washout period for immunotherapy pretransplant?	Although there are no strong data on the safe time interval, the recommendation with respect to a washout period of 2–3 half-lives of the specific ICI regimen, until the results of ongoing clinical trials are available.	Weak	Moderate
Should post-LT immunosuppression be different in those who received immunotherapy prior to LT to avoid rejection?	At this time, there are not enough data available to support the use of a particular immunosuppression regimen when assessing the risk of liver rejection. The decision on which regimen to adopt should be made on a case-by-case basis, according to the clinical judgment of the center's multidisciplinary team.	Weak	Weak
What is the safety and rationale to combine locoregional therapies, immunotherapy, and tyrosine kinase inhibitors in patients on the waiting list?	There is limited evidence in the literature to support the use of combining locoregional therapy, ICIs, and tyrosine kinase inhibitors (TKIs) in patients who are eligible for liver transplantation and are on the waiting list. Until new data are available, we recommend LRT should be preferred alone and not in combination with other therapies as bridging therapy.	Weak	Strong
Working Group D: Deceased Donor (DDLT) vs. Living Donor Liver Transplantation (LDLT)			
Should the indications for LDLT for liver tumors be different from those for DDLT among centers that are predominantly LDLT?	Both tumor burden and biology (AFP, DCP, FDG-18 avidity alone or in combination) can be considered while selecting any patient for liver transplantation. However, the selection criteria for transplantation for HCC can be different in LDLT-predominant regions, respecting the principles of "double equipoise" and transplant benefit in LDLT, after locoregional therapy and response.	Low	Moderate
Should the indications for LDLT for liver tumors be different from those for DDLT in patients with HCC outside Milan criteria?	While the ethos of downstaging (DS) in LDLT and DDLT are different, the same downstaging criteria should be applicable for LDLT as it is for DDLT. The ability to time transplantation in LDLT provides an intention-to-treat advantage. In LDLT, transplantation timing is driven more by the response to therapy rather than the actual wait time to obtain an organ (DDLT).	Moderate	Moderate
Should downstaging be treated differently for patients undergoing LDLT vs. DDLT?	After successful downstaging, it is recommended that patients have tumor stability for at least 3 mo before proceeding with LDLT, which is the same for patients waitlisted for DDLT.	Moderate	Moderate
Should patients with macrovascular invasion be considered for LDLT, and should selection criteria be different than DDLT?	HCC patients with macrovascular invasion can be considered for LDLT after successful downstaging, and within an a priori protocol. The selection criteria for LDLT in HCC patients with macrovascular invasion include no extrahepatic disease, an AFP (and DCP) cutoff, PET non-avid tumor, and response to downstaging therapy to ensure acceptable tumor biology.	Low	Moderate
Should LDLT be considered in patients with iCCA?	The available literature suggests that the indications for LDLT in iCCA could cautiously align with those for DDLT, particularly in very early-stage cases.	Low	Moderate
Is LDLT inferior or superior to DDLT for HCC? Should it be acceptable for expected overall and recurrence-free survival rates to be lower for LDLT than for DDLT?	Given that the outcomes with regards to overall and disease-free survival are on-par and, in certain cases, better than DDLT, LDLT should be considered as an oncologically durable and safe alternative to DDLT. In regions where the waiting time (>3 mo) or where LDLT is the predominant type of LT, LDLT may be a preferred option for HCC within and beyond standard criteria.	Moderate	Moderate

TABLE 1. (*continued*)

Question	Recommendation	Level of evidence	Strength of recommendation
Working Group E: Post-Transplant Management			
What should be the optimal follow-up and modality for cancer recurrence surveillance?	Post-LT recurrence risk stratification is recommended using validated risk models developed from multicenter studies.	Moderate	Strong
What should be the optimal follow-up and modality for cancer recurrence surveillance?	Surveillance for intermediate- to high-risk individuals is recommended at a minimum of every 6 mo with cross-sectional contrast-enhanced imaging of chest, abdomen, and pelvis.	Moderate	Strong
What should be the optimal follow-up and modality for cancer recurrence surveillance?	Post-LT testing of serum AFP is recommended in high-risk individuals with elevated serum AFP pretransplant, but the timing interval is unclear.	Moderate	Strong
What is the optimal immunosuppression for patients transplanted for liver cancer?	Exposure to high CNI levels, especially in the early post-LT period, should be avoided if possible. Induction immunosuppression post-LT does not appear to influence the incidence of HCC recurrence and should not be avoided for this reason. Use of mTORi and reduced dose CNIs should be considered.	Moderate	Strong
What is the best course of management for posttransplant cancer recurrence?	Surgical resection of isolated HCC recurrence after LT leads to improved survival compared to palliative treatment or best supportive care and should be attempted whenever feasible. For recurrences where surgery is contraindicated or not feasible, locoregional therapies or radiotherapy can be considered where technically feasible.	Moderate	Strong
What is the role of adjuvant systemic treatment?	Based on existing evidence, the routine use of adjuvant systemic therapy after LT for HCC is not recommended outside of a clinical trial.	Moderate	Strong
What is the role of systemic treatment at the time of recurrence?	TKIs are effective and safe for patients with HCC recurrence after LT and may be used in this setting.	Moderate	Strong
	ICIs have been associated with the risk of graft rejection but may be cautiously considered within a clinical ICI/immunosuppression protocol or clinical trial.	Weak	Moderate
What is the role of ischemia-reperfusion injury and machine perfusion in the risk of recurrence?	Based on existing evidence, liver graft allocation and management strategies (including machine perfusion) should not be modified for patients with HCC to reduce the incidence of recurrence. Although the link between ischemia-reperfusion injury and HCC recurrence is supported by convincing preclinical data, clinical evidence is weak and deserves validation.	Weak	Moderate
Is there a difference in recurrence depending on the etiology of liver disease or the type of donor?	Based on existing evidence, no recommendation can be made for donor-recipient matching to influence the incidence of HCC recurrence or its prognosis based on factors including donor age, sex, DCD vs. DBD, and etiology of recipient liver disease.	Weak	Moderate
Working Group F: Role of Liver Transplantation for Intrahepatic Cholangiocarcinoma (iCCA)			
What is the role of transplant in cirrhotic patients with intrahepatic cholangiocarcinoma?	In cirrhotic patients with iCCA, liver transplantation may be considered as a potential therapeutic option in tumors ≤ 3 cm in diameter after a period of observation with stability and without extrahepatic metastasis, as it offers a chance of curative treatment and improved survival.	Moderate	Moderate
		Moderate	Weak

What is the role of transplant in non-cirrhotic patients with intrahepatic cholangiocarcinoma? Is there any limitation of size and number?	In non-cirrhotic patients with intrahepatic cholangiocarcinoma, liver transplantation is not routinely recommended but may be considered as part of investigational protocols for patients with unresectable, liver-confined disease after at least 6 mo of stability after systemic therapy. Limitations on tumor size and number should be explored in prospective clinical trials.		
What is the role of biopsy and molecular profiling in selecting candidates for LT for iCCA?	Tumor biopsy should be mandatory to confirm the diagnosis of iCCA and assess tumor differentiation. Molecular profiling is indicated in the management of iCCA; however, there is no evidence to recommend use in liver transplant patient selection.	Low	Moderate
What is the role of neoadjuvant therapies (chemotherapy, targeted therapies, immune checkpoint inhibitors) in LT for iCCA?	Bridging with neoadjuvant therapies may help to identify patients with favorable tumor biology who might be considered for liver transplantation for unresectable iCCA (>6 mo disease stability or successful downstaging of disease).	Low	Weak
Should patients receiving immune checkpoint inhibitor therapy be considered for LT for iCCA?	In patients treated with palliative intent who have had a favorable response or stable disease, with liver-confined, unresectable disease, the receiving ICI therapy should not preclude consideration of transplantation, and these patients should be referred to a transplant center if eligible.	Low	Weak
What are the best biomarkers for response to therapy and post-LT monitoring?	Tumor markers, including CA19-9 and CEA, may be considered for response assessment and posttransplant monitoring in patients with iCCA. Given limited data on the utility of novel biomarkers for response and posttransplant monitoring in iCCA, their use is currently not routinely recommended outside of clinical trials.	Low	Weak
Working Group G: The Patient's Perspective			
	There is a need for cancer-specific health-related quality of life (HRQOL) and psychological outcomes (and evaluable by HCC vs. CCA).		
	There is a need for standardization of a liver transplantation quality of life tool.		
	In addition to the patient, further evaluation of the impact of transplantation on caregivers is needed.		

Abbreviations: AFP, alpha-fetoprotein; CA19-9, carbohydrate antigen 19-9; CCA, cholangiocarcinoma; CEA, carcinoembryonic antigen; CEUS, contrast-enhanced ultrasound; CNI, calcineurin inhibitor; DBD, donation after brain death; DCD, donation after circulatory death; DCP, des-γ-carboxy prothrombin; DDLT, deceased donor liver transplantation; FDG-18 or FDG, ^{18}F-fluorodeoxyglucose; HRQOL, health-related quality of life; iCCA, intrahepatic cholangiocarcinoma; ICI, immune checkpoint inhibitor; LDLT, living donor liver transplantation; LI-RADS, Liver Imaging Reporting and Data System; LRT, locoregional therapy; MASLD, metabolic dysfunction–associated steatotic liver disease; mRECIST, modified response evaluation criteria in solid tumors; mTORi, mammalian target of rapamycin inhibitor; PET, positron emission tomography; TKI, tyrosine kinase inhibitor; US, ultrasound.

limited in some patients, these noninvasive screening methods are currently the best way to screen for HCC.

In addition, although biopsy is not routinely needed in patients with HCC, it should be utilized in patients with inconclusive imaging to rule out iCCA features and metastatic liver disease to the liver. At present, there is no evidence that the so-called "liquid biopsy" with circulating tumor DNA has utility in patient selection for LT. Evidence regarding the diagnostic performance of circulating tumor DNA is weak and dependent on the technology, although future work may show it has prognostic value in the transplant setting.[19]

Participants recommended against absolute age limits for LT for HCC who otherwise meet criteria for LT at one's center. Although older patients are frequently more frail, posttransplant patient and graft survival rates are statistically similar in propensity-matched patients.[20] Attendees agreed that LT should be restricted to patients with unresectable disease and who are expected to have adequate post-LT survival ($\geq$50% at 5 y). Evaluation and treatment of patients should be similar, regardless of the etiology of background liver disease, for example, metabolic dysfunction–associated steatotic liver disease versus other etiologies.

LT should be reserved for patients with unresectable disease or disease not amenable to curative ablation. Resection should be considered for patients with good performance status and a single lesion. In addition, patients with HCC recurrence after adequate, effective, complete tumor removal with the intent for a cure should be considered for transplantation. In these cases, living donor LT (LDLT) should be preferred, if possible, to prevent dropout from transplantation once HCC recurrence is diagnosed to improve the graft pool for the other patients. However, in those with early recurrence (within 6 mo after pre-LT treatment), LRT should be used to ensure tumor control before transplantation.

Working group B: Criteria for listing patients with HCC

Regarding selection criteria for patients with HCC, there were multiple points of contention among various experts based on their local practices. The final recommendations endorse moving away from size-and-number-based selection criteria (Milan criteria) and instead selecting patients based on tumor biological behavior (Table 1). However, it was agreed upon that it is imperative to not only assess individual-level benefits but also consider the broader population-level impact so as to not inadvertently disadvantage patients without HCC. Multiple studies have demonstrated excellent post-LT survival in patients outside standard size-based criteria using biomarkers and response to pretransplant therapy as selection criteria (Table S1).[9–11] Some scores have been proposed to equate priority in the WL for patients with HCC and without HCC (Supplemental Table SB1, http://links.lww.com/LVT/A906) based on balancing the risk of WL dropout (DO) for both groups of patients and/or transplant benefit survival. Patients who are at very high risk of poor outcomes (patients with AFP $>$1000 ng/mL, progressive disease despite therapy, or worsening liver function) should receive additional scrutiny during evaluation.

In assessing an individual's survival benefit of LT with HCC, models have been recommended to specifically address post-LT survival related to HCC recurrence, which remains the number one cause of mortality in such patients. The Metroticket 2.0 scale helps determine the post-LT mortality derived from HCC-related events, using a combination of size and number of nodules, along with AFP.[11] Similarly, a large European intention-to treat survival benefit analysis by Lai et al[21] identified 4 risk factors that identified patients unlikely to benefit from LT: progressive disease or complete response after neoadjuvant therapy, most recent AFP $\geq$1000 ng/mL, being within Milan criteria, and low MELD ($\leq$13). Conference participants noted the importance of such models, but did not recommend the utility of one model over another.

The literature reflects a growing interest in recognizing other complementary biomarkers other than AFP, such as lectin-bound AFP % (AFP-L3%) and des-gamma carboxy prothrombin (DCP).[22] Elevated AFP-L3 and DCP have been associated with more aggressive HCC[23,24] and worse post-LT outcomes.[22,25,26] AFP-L3 and DCP outperform AFP in the prediction of WL dropout and early HCC recurrence (C-statistics of 0.81 and 0.86, compared to 0.74 for AFP).[27] Moreover, the combination of AFP-L3 $>$15% and DCP $>$7.5 ng/mL had significantly worse 3-year recurrence-free survival and was correlated with all high-risk features at explant pathology. The combination of AFP-L3 $\geqq$35% and DCP $\geqq$7.5 ng/mL has recently been shown to predict 100% WL dropout.[28] In addition, drop-out risk scores have been developed; one such validated score incorporates 4 tumors (tumor size/number, AFP) and liver-related factors (eg, MELD-Na, Child-Pugh) at the time of listing, and was able to stratify 1-year dropout risk ranging from 7% to 40%.[29]

The BALAD-2 model, combining liver function parameters and biomarkers (bilirubin, albumin, AFP, AFP-L3%, and DCP), has been shown to be useful in predicting HCC-related survival.[30,31] Neutrophil-to-lymphocyte ratio (NLR), an inflammatory marker, has also been correlated with poor prognosis and HCC recurrence, in East Asian regions,[32] and is included in several recurrence prediction models (preMORAL, UCLA Nomogram, and RELAPSE score).

The need for bridging depends on the available organ pool, the expected waiting time for deceased donor LT (DDLT), and the availability of LDLT. Bridging

therapy should be offered to candidates expected to have long wait times (>6 mo to receive LT, now standard in some parts of the world) and with more aggressive tumors (high/increasing AFP, rapid interval growth). There is insufficient evidence to recommend one LRT modality over another. Studies comparing transarterial chemoembolization (TACE) versus transarterial radioembolization in waitlisted patients have demonstrated similar post-LT outcomes, including recurrence free survival and OS,[33] but a recent UNOS analysis demonstrated transarterial radioembolization or ablation as first LRT was associated with decreased risk of waitlist dropout compared to TACE.[34] transarterial radioembolization is more cost-effective than TACE in waitlisted patients with HCC exceeding Milan criteria.[35] Single-arm studies evaluating stereotactic body radiation (SBRT) have demonstrated response rates comparable to other bridging modalities without significant radiation-related operative complications.[36] Those who undergo bridging therapy on the waitlist should be monitored at 1 month and 3 months after treatment and at 3-month intervals thereafter.

Downstaging treatment can be offered to patients outside standard selection criteria if there is no extrahepatic disease. The goal of downstaging should be to reduce tumor burden and/or biomarker levels to be within the center's criteria, and it is critical to define successful downstaging before treatment. Post-LT outcomes in patients who have been downstaged are not significantly different when compared to those that began within Milan criteria. It is recommended that centers use Modified Response Evaluation Criteria in Solid Tumors (mRECIST) and/or Liver Imaging Reporting and Data System (LI-RADS)-R criteria to assess treatment response. Complete response to pre-LT therapy is preferred over partial response when possible.[22] Patients undergoing downstaging should be observed for a minimum of 3 months before LT to assess disease stability. Most published downstaging studies have used Milan criteria as the endpoint, yet considerable debate surrounds the dichotomous nature of Milan criteria, which may preclude LT in patients with larger tumors that might have otherwise acceptable post-LT outcomes.

A recent analysis of the UNOS database found that patients beyond UNOS-DS (unrestricted tumor size and number, without macrovascular invasion [MVI] or extrahepatic disease), called all comers (AC), are at significantly higher risk for waitlist dropout within 2 years compared to those within MC and UNOS-DS.[37] AC with an AFP >100 ng/mL experienced drop rates exceeding 50% at 2 years. Identified predictors of dropout are poor liver function (Child-Pugh B/C) and the sum of tumor number and largest tumor diameter >8 cm.

MVI, seen in up to a third of patients with HCC, has historically been considered a contraindication to LT for HCC given the high risk of HCC recurrence leading to significantly worse survival (up to 5-fold higher mortality). However, patients with MVI are a heterogeneous group with prognosis (response to resection or LRT, post-treatment survival) dependent on the extent of the portal vein tumor thrombus,[38,39] tumor volume,[40] and AFP.[41] Portal vein tumor thrombus of Vp3 or Vp4 is associated with significantly worse prognosis compared to Vp1 or Vp2.[39] LRT and/or systemic therapy may yield complete radiologic and/or biochemical response in patients with MVI leading to a potential window for LT. Data are limited on downstaging outcomes in patients with MVI; most studies are small, retrospective, and prone to selection bias. In a multinational cohort study of 30 patients transplanted with MVI, 5-year OS was 60%. Patients who underwent DS with AFP <10 ng/mL at LT had a recurrence rate of 11%. There are few data outside of case reports/series reporting outcomes on DS with immunotherapy in patients with MVI.[42] The optimal preoperative or DS treatment has not yet been identified; prospective and comparative studies are needed in this area.

Working group C: Immunotherapy and liver transplantation

The recent approval of new immunotherapy (IO) drugs to treat liver cancer has led to interest in IO as neoadjuvant therapy for candidates for LT. Two trials have established new standards in advanced HCC: IMbrave150 trial with atezolizumab + bevacizumab versus sorafenib[43] and HIMALAYA trial with single dose tremelimumab + durvalumab (STRIDE) versus sorafenib.[44] The mOS using atezolizumab + bevacizumab was 19.2 months (95% CI, 17.0–23.7), with STRIDE 16.4 months (95% CI, 14.2–19.6), with camrelizumab + rivoceranib (CARES-310) 23.8 months (95% CI, 20.6–27.2)[45] and with nivolumab + ipilimumab (Checkmate 9DW trial) 23.7 months (95% CI, 18.8–29.4).[46] The objective response rates (ORR) were 30%, 21%, 27%, and 36%, respectively. The EMERALD-1 trial demonstrated a progression-free survival benefit of 6.8 months (HR, 0.77; 95% CI, 0.61–0.98; $p = 0.032$) when combining TACE + durvalumab/bevacizumab versus TACE alone.[47] The ORR was 44% for the combination arm versus 30% for TACE alone. While patients in this trial were not included if eligible for transplant, these data suggest that combination approaches could provide a potential opportunity for downstaging to LT.

While there have been several case reports supporting this practice, unfortunately, there is a lack of robust evidence surrounding the use of IO as a neoadjuvant therapy for LT (Supplemental Table C1, http://links.lww.com/LVT/A906). Therefore, consensus members were unable to make recommendations regarding the preferential use of any IO drug in the LT setting or groups of patients, such as those with PVT.[48] They suggested

waiting to make a recommendation on the utilization of one IO therapy over another until data from ongoing prospective studies are available.

Instead, recommendations emphasized the importance of center-level multidisciplinary decision-making until more evidence is available. The group recognized that patients who in the past were not eligible for LT (ie, with MVI), if a sustained response to IO in combination or not with LRT is achieved, may be considered for transplant on a case-by-case review. When a sufficient response to downstaging has not been achieved, IO should be considered to increase response rates and rates of LT while improving oncologic outcomes. It is recommended that patients undergoing pre-LT immune checkpoint inhibitor therapy have a washout period of 2–3 half-lives of that drug before receiving LT to minimize the risk of posttransplant rejection.[49] Evidence suggests a washout period of at least 60 days for bevacizumab to account for its effects on wound healing.[50] It is important to note that IO still carries many risks when utilized in the transplant setting, and there is a possibility of adverse events even with the aforementioned washout period. Only a period of 5 half-lives will guarantee washout of the IO agent.[51] Research has shown a single dose of nivolumab can remain bound to lymphocytes for up to 100 days.[52] Also, some patients treated with IO may achieve complete radiologic response, but at the current time there is not enough evidence to (a) suggest that these patients no longer need a transplant and (b) suggest a period of observation without IO pretransplant (besides the mentioned washout period).

This conference highlighted the need for more prospective clinical trials before stronger recommendations can be made. A table of current prospective trials is summarized in Supplemental Table SC1, http://links.lww.com/LVT/A906.

Working group D: Living donor versus deceased donor liver transplantation

While utility (maximizing survival) and equity (equitable access to scarce deceased donor organs) are the guiding principles in DDLT, maintaining "double equipoise" (maintaining acceptable recipient outcomes and donor safety) and transplant benefit (incremental survival benefit with transplantation compared with the best non-transplant option) drive selection of transplant oncology patients for LDLT. Working group members and consensus participants agreed that recipient selection criteria for patients undergoing LDLT and DDLT can differ. Given the excellent survival outcomes after LDLT versus DDLT noted by intention-to-treat studies,[53–55] LDLT may be preferable in areas with long wait times for DDLT (Supplemental Table SD4, http://links.lww.com/LVT/A906). The need for double equipoise in LDLT does not preclude different selection criteria as long as donor and recipient safety are prioritized.

The recommended overall pretransplant recipient management of candidates for LDLT is similar to candidates for DDLT.[56] Downstaging should be driven by response to therapy, with radiographic tumor stability ≥ 3 months before proceeding with LDLT. Given that LDLT is available sooner than DDLT in most jurisdictions, once response to treatment is achieved (to provide some insights into tumor biological behavior) a shorter waiting period is allowed. Despite the lack of direct evidence in recipients of LDLT, participants recommended that carefully selected patients with high-risk HCC, such as patients with MVI at diagnosis who have achieved radiographic response and decline in AFP, may undergo LDLT under strict predefined center protocols. LDLT for iCCA may also be considered under institutional protocols, particularly in patients with early-stage disease.[57] In the setting of LT for advanced HCC beyond standard criteria, ethical arguments may be made that such patients should not be afforded retransplant with either a deceased or living donor. Such arguments are not supported by data suggesting such patients can do well after LT with advanced disease.

Working group E: Posttransplant management

Given that posttransplant recurrence is strongly linked to overall survival, it is important to identify patients who are likely to recur so they can undergo enhanced surveillance after LT.[58] Many models for estimating post-LT recurrence have been proposed, which generally incorporate high-risk features such as tumor burden, pathologic differentiation, vascular invasion, and biomarkers. The consensus did not recommend one recurrence risk score over another, but instead emphasized the importance of using externally validated models for risk stratification. Posttransplant surveillance is important in these patients, and regular recurrence screening is associated with a higher probability of receiving treatment with curative intent and improved post-recurrence patient survival. Patients who are at moderate- or high-risk of recurrence should undergo contrast imaging of the abdomen, chest, and pelvis at least every 6 months. AFP serum levels can also be used to monitor for recurrence in conjunction with imaging.

Optimal immunosuppression regimens for recipients of LT with a history of cancer have been a topic of research and debate due to their potential to promote recurrence. Currently, there is no contraindication to the use of induction immunosuppression in patients undergoing LT for primary liver cancer.[59] High levels of

exposure to calcineurin inhibitors should be avoided in the early post-LT period if possible, and their maintenance levels should be minimized thereafter. Utilization of mammalian target of rapamycin (mTOR) inhibitors should be considered, which some evidence suggests may reduce recurrence risk,[60] but we did not make an explicit recommendation to use these drugs in this population.

There are no standardized treatments for posttransplant cancer recurrence. If a patient experiences post-LT recurrence, resection, if feasible, provides the best long-term survival outcomes. Systemic therapies can be used if the recurrence is unresectable, including tyrosine kinase inhibitors, which are generally considered safe in the post-LT population.[61] Posttransplant use of immune checkpoint inhibitors should be considered cautiously and only in the context of a clinical protocol given the high risk of rejection. However, this is an unmet need as the outcomes of these patients are otherwise dismal. Most studies do not support the efficacy of adjuvant therapies such as kinase inhibitors to reduce the risk of recurrence.

The working group and participants agreed that there is no high-quality evidence that donor demographics or deceased donor type (donation after circulatory vs brain death) affect recurrence risk.[62] Despite preclinical data suggesting that ischemia-reperfusion injury may be associated with recurrence,[63] strong clinical evidence is lacking, and therefore no recommendations regarding graft ischemia were made. Although some initial studies have suggested that machine perfusion may reduce the risk of HCC recurrence, no recommendations were made regarding their use as a recurrence mitigation strategy.

Working group F: Role of liver transplantation for intrahepatic cholangiocarcinoma

LT for iCCA has been a contentious topic, particularly for patients whose tumors have grown beyond a "very early" stage.[13] Transplantation is reserved for patients with unresectable iCCA lesions and favorable tumor biology. Most reports describing outcomes after LT for iCCA have been single-center retrospective studies, limiting their applicability to a wider population (Supplemental Table C1, http://links.lww.com/LVT/A906). Modern 5-year posttransplant survival outcomes range between 25% and 73% overall survival and 29% and 82% recurrence-free survival.

However, the consensus conference highlighted a broad agreement throughout the community that LT for iCCA should be offered to patients with cirrhosis and small single tumors (≤ 3 cm in diameter). All candidates for LT with presumed iCCA should undergo a liver biopsy to confirm the diagnosis and rule out mixed hepatocellular-cholangiocarcinoma. A biopsy can also help identify poorly differentiated tumors with a high risk of recurrence, which may factor into multidisciplinary decision-making. Centers may consider using biomarkers such as carbohydrate antigen 19-9 or carcinoembryonic antigen to assess tumor burden and biology based on local practice guidelines. Tumor markers in conjunction with cross-sectional imaging have been shown to accurately identify patients with recurrent iCCA.[64] It is important to note that the role of LT for large unresectable iCCA or locally advanced iCCA or in patients without cirrhosis was controversial among consensus conference participants and no agreement was reached regarding LT in this population.

Tissue-based molecular profiling with comprehensive next-generation sequencing is recommended for patients with unresectable or metastatic iCCA who are considered for systemic therapy[65] since actionable molecular targets are found in 40%–50% of iCCA.[66] At present, no recommendation can be made for the use of liquid biopsy for post-LT monitoring; however, the field is rapidly evolving.[67]

Preoperative systemic therapy is a potential option for candidates for LT with iCCA, with gemcitabine-based regimens being the preferred option in literature.[14,68] However, the role of novel targeted therapies in the perioperative setting will likely expand soon, with potential implications in the peritransplant setting for patients with iCCA.[69] A period of at least 6 months of disease stability on treatment can select patients with a more favorable outcome, thus helping to identify potential candidates to LT.[14,68] Although immune checkpoint inhibitors have not been directly studied in transplant patients with iCCA, the consensus was that their use should not rule out the possibility of transplant given a proper washout period (see Supplemental Material, Section C, http://links.lww.com/LVT/A906). Prospective clinical trials of neoadjuvant therapy in patients with iCCA are underway and will provide important evidence for therapy selection in patients with small unresectable tumors, as well as the potential expansion of LT to patients with locally advanced iCCA lesions that respond well to neoadjuvant therapy (Supplemental Table SF2, http://links.lww.com/LVT/A906).

Working group G: The patient's perspective

The seventh working group was tasked with reviewing patient experience with LT for HCC and iCCA, including questions surrounding access to care and post-LT quality of life. The patient's perspective is critical for positive outcomes in the field of transplant oncology. Their systematic review revealed that there is a dearth of evidence surrounding health-related quality of life in

this patient population, particularly in patients with cholangiocarcinoma. Posttransplant patient management can also affect quality of life, with factors like frequent medication changes adding additional stress to patients' lives.[70]

The recommendations from this group highlighted the need for better and standardized cancer-specific and LT-specific health-related quality of life outcomes that relate to patients undergoing LT for HCC and iCCA. Standard-validated psychological questionnaires also often miss many aspects that are important to these patients. However, it is important to note that although no specific health-related quality of life questionnaires are available for this patient population, any validated QOL measure utilized in these patients would provide valuable insight. Additional data on patient-reported outcomes in patients undergoing LT for liver cancer are desperately needed to adequately address the full spectrum of medical and non-medical outcomes in this population. They also recommended additional research be performed into the impact of LT on the caregivers of patients with HCC and iCCA.

DISCUSSION

The 2024 ILTS-ILCA Consensus Conference on LT for HCC and iCCA highlighted many advancements in the field of transplant oncology. There was broad support for increasing access to LT for primary liver cancer while still maintaining ethical principles of utility and justice. Many participants emphasized the importance of center-level selection criteria and protocols, arguing that cutoffs should be decided by each center's multidisciplinary LT teams. There was also increased support for the role of LT in patients with cirrhosis and iCCA, but not for patients with more locally advanced diseases.

The conference highlighted several areas of opportunity for future research. More prospective multicenter studies and clinical trials are needed to elucidate optimal pretransplant and posttransplant management of these patients. More data are needed surrounding the role of immunotherapy in these patients, both before and after LT. More work is also needed to determine optimal downstaging strategies and endpoints, the most accurate biomarkers to gauge tumor biology before LT, and the most effective treatments for recurrence. Given the growth in machine perfusion over recent years, research is also needed to determine whether its use might improve outcomes in recipients of LT with primary liver cancer. Future studies should also investigate how to safely expand access to LDLT for these patients, given the deceased donor shortage in most parts of the world.

In summary, the field of transplant oncology and the landscape of LT for HCC and iCCA are evolving rapidly. There has been a general shift away from size-based patient selection criteria toward an integrated assessment of tumor biology and aggressiveness. New doors have also opened in the neoadjuvant therapy arena, potentially opening the doors to transplant to more patients whose lesions respond to these therapies. Further development of models of biomarkers for recurrence will allow transplant centers to more accurately identify patients who are most likely to benefit from LT. Through this collaborative work, current and future advances will allow more patients with HCC and iCCA to access LT in the future.

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ILTS ILCA CONSENSUS GROUP

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CONFLICTS OF INTEREST

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