

EN HEPATOLOGÍA

PROGRAMA DE DOCTORADO

Biomedicina, Investigación Traslacional y Nuevas Tecnologías en Salud.

Liver transplantation in 2024

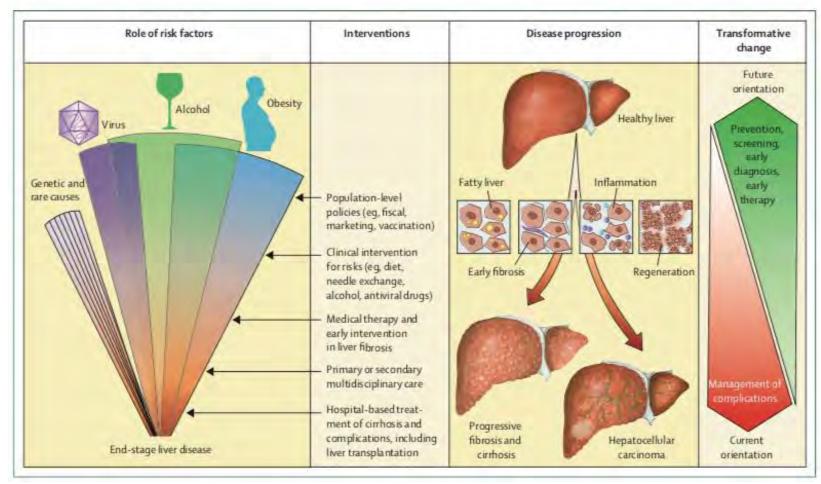
Patrizia Burra Gastroenterology Multivisceral Transplant Unit Department of Surgery, Oncology and Gastroenterology Padua University Hospital Padua Italy

Outline

- Severe alcohol-related hepatitis
- Metabolic dysfunction-associated steatotic liver disease
- Acute-on-chronic liver failure
- Transplant oncology
- Novel approaches



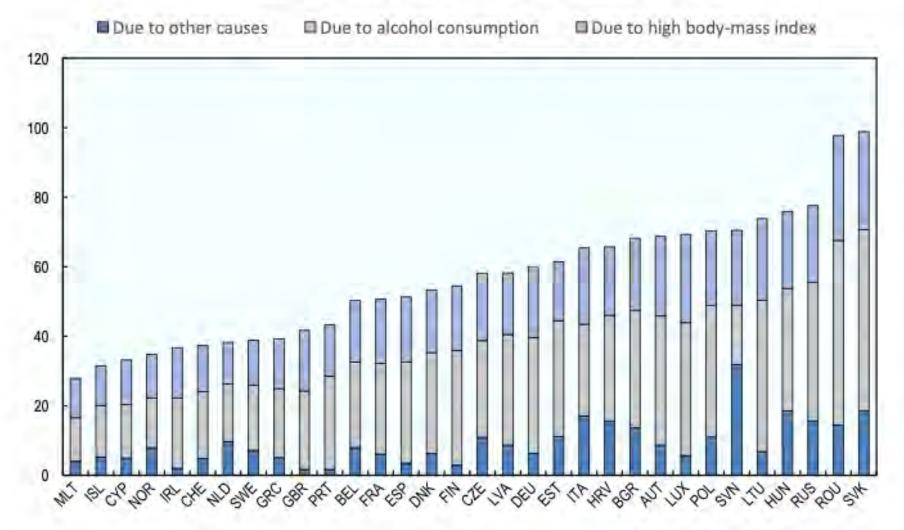
Risk factors for liver disease in Europe



Karlsen, Burra, Manns – The Lancet 2021



Premature deaths due to liver diseases, per 100 000, average 2020-2050

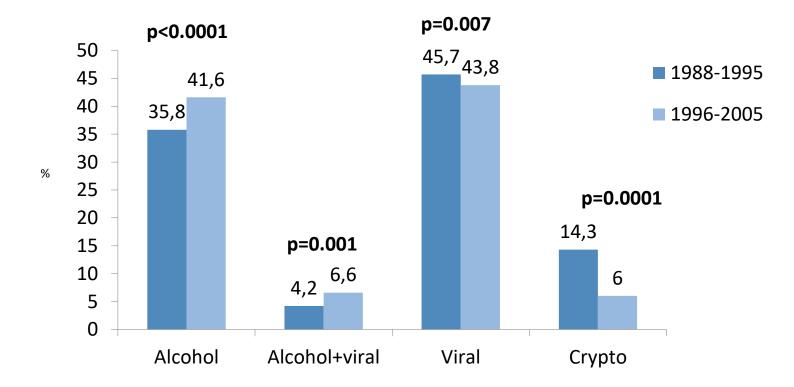


Karlsen, Burra, Manns – The Lancet 2021

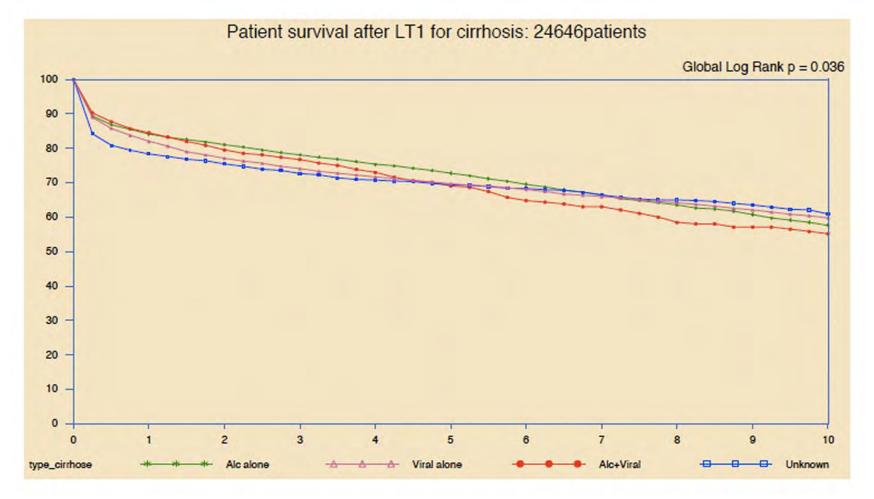
doi: 10.1111/j.1600-6143.2009.02869.x

Liver Transplantation for Alcoholic Liver Disease in Europe: A Study from the ELTR (European Liver Transplant Registry)

P. Burra^{a,*}, M. Senzolo^a, R. Adam^b, V. Delvart^b, V. Karam^b, G. Germani^a, J. Neuberger^c, for ELITA and of behalf of ELTR Liver Transplant Centers^d



Patient survival after liver transplantation according to liver disease in Europe (ELTR-ELITA data)



Burra P. Am J Transpl 2010

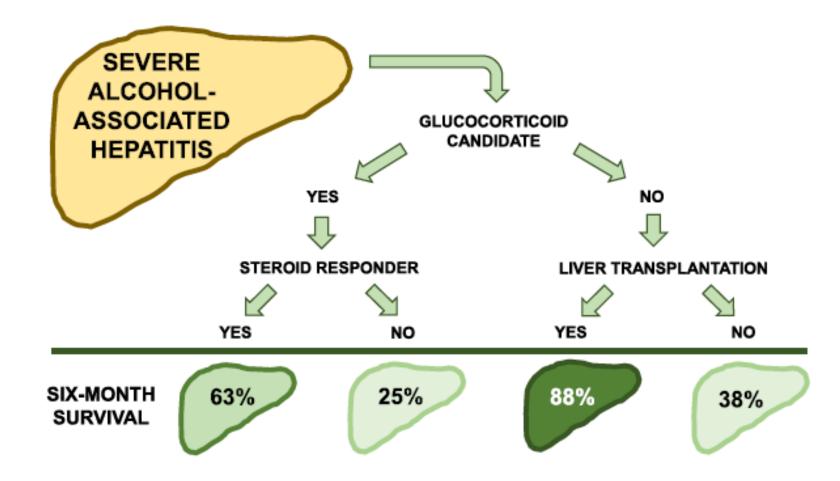
Medical management of severe alcohol-related hepatitis

Minimal progress has been made in the medical management of these patients.

Abstinence, nutrition, prevention/treatment of infections and corticosteroids remaining the mainstay of therapy since the 1970s.

Ramirez-Cadiz et al. Alimentary Pharmacology & Therapeutics 2024

Differential 6-month survival in severe alcohol-related hepatitis



Horwich, Clinical Liver Disease 2023

Selecting the patient for early-liver transplantation

- Stringent patient selection criteria:
 - Maddrey's discriminant function of at least 32
 - Steroid non-response, according to the Lille score of 0.45 or more at day 7 or a continuous increase in the MELD score patient's first decompensating event
 - Presence of close, supporting family members
 - Absence of psychiatric disorders
 - Agreement of the patient to adhere to lifelong abstinence from alcohol use

The 2022 QuickTrans:

Scoring algorithm to select candidates for early liver transplantation

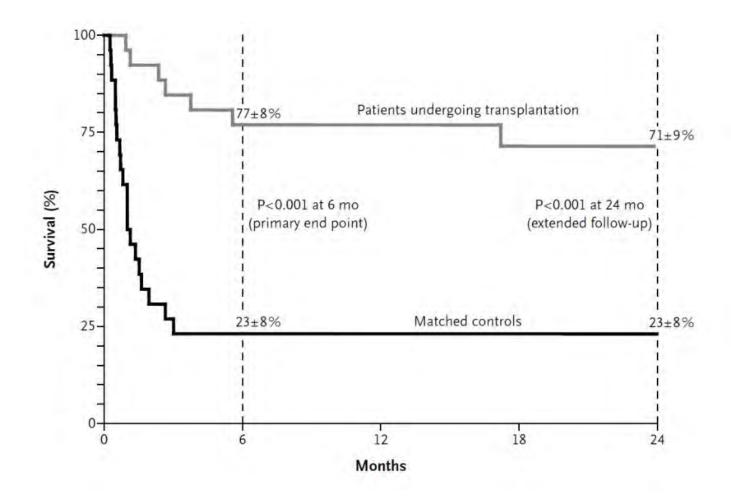
It contains:

- somatic criteria (severe comorbidities and prior liver decompensation)
- global evaluation by addiction specialists (assessment of psychiatric disease, family support)
- evaluation by the liver team (patient motivation, medical adherence, insight, support system, alcohol problems in relatives, questions asked by relatives)
- subjective evaluation of the adaptability of the candidate

Scores range from 0–250

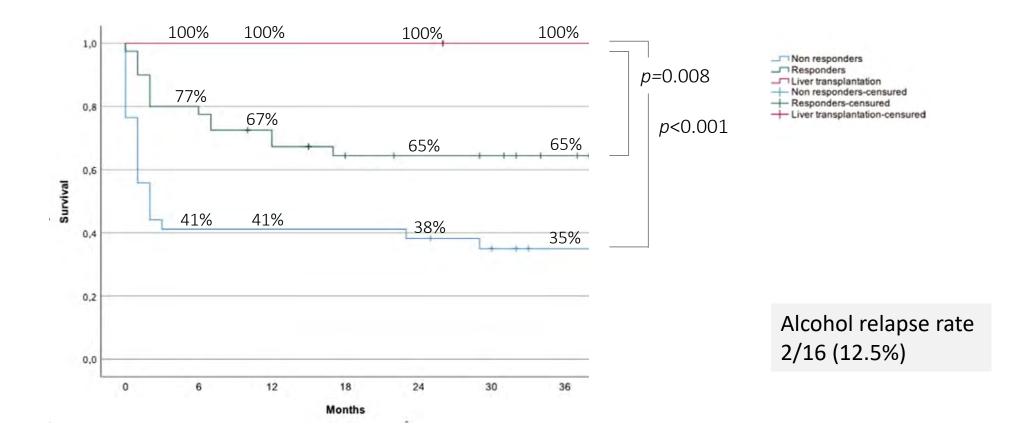
Patients receiving scores between 220–250 eligible for early liver transplantation

Early Liver Transplantation for Severe Alcoholrelated Hepatitis



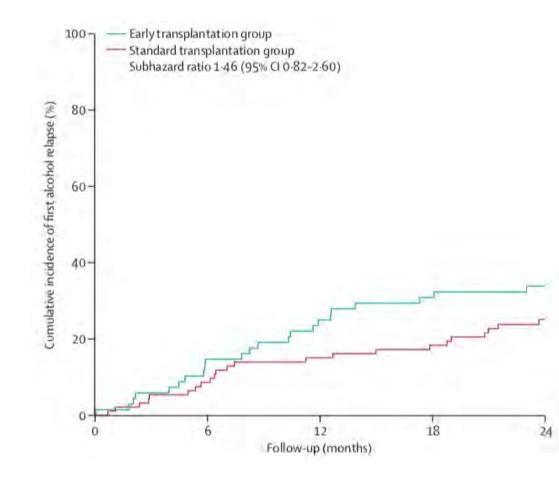
Mathurin P, et al. N Engl J Med 2011;365:1790

93 referred patients, with severe alcohol-related hepatitis, 16 transplanted: estimates of survival among the transplanted vs non transplanted according to the response to medical therapy



Germani G, et al. Am J Transpl 2022;22:1191

2-year cumulative incidence of first alcohol relapse after liver transplantation in the early transplantation (LT) group and standard transplantation group

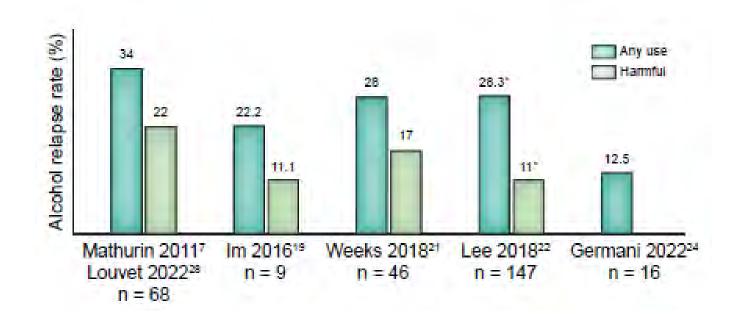


Alcohol relapse rate:

Early LT: 23/68 (34%) patients Standard LT: 23/93 (25%) patients Absolute difference of 9.1% (95% CI -∞ to 21)

Louvet A, et al. Lancet Gastroenterol Hepatol 2022;7:416

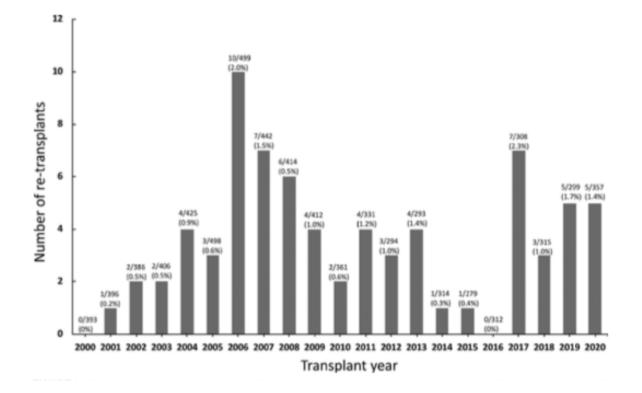
Rates of return to alcohol use in studies on early liver transplantation for severe alcohol-related hepatitis



Germani G, Mathurin P, Lucey MR, Trotter J, Journal of Hepatology 2023

The Practice of Retransplantation for Recurrent Alcohol-associated Liver Disease (ALD) in the United States Is Uncommon With Acceptable Outcomes

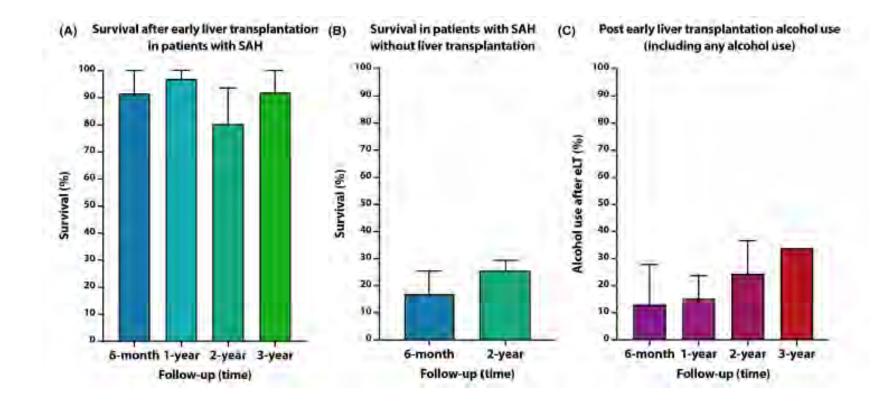
- US national transplant registry (2000-2020)
- 74 retransplantation (1.0% of all retransplants) for recurrent ALD
- Patient survival was similar between patients who underwent retransplantation for ALD and non-ALD (63% versus 59% 5-y, *P*=0.58)



• The practice is uncommon in the US

Cotter Transplantation Direct 2022

Early liver transplantation for severe alcohol-related hepatitis: excellent outcomes



Ramirez-Cadiz et al. Alimentary Pharmacology & Therapeutics 2024

General population measured attitudes towards early liver transplantation for severe alcohol-related hepatitis

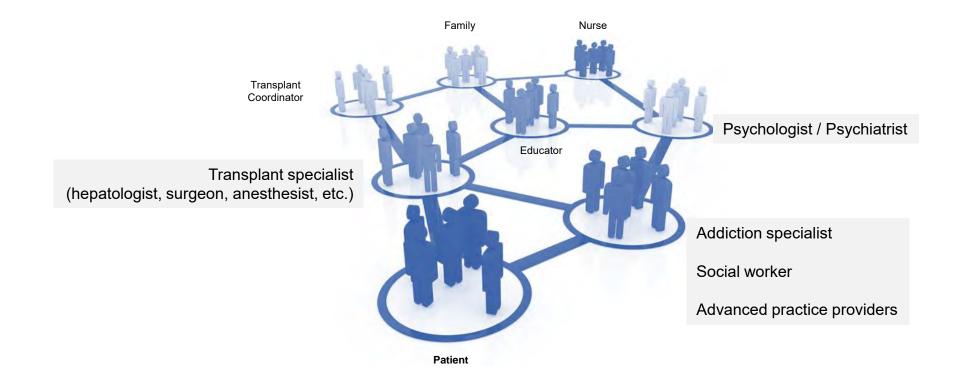
- Online survey in the U.S.
- 503 respondents
- 81.5% were at least neutral towards early transplantation for these patients
- Public opinion may not be as large of a barrier as originally thought

The hepatology toolbox—how do we include alcohol use disorder treatment?

?Knowledge ?Time ?Access When it comes to the **Alcohol Use** HEPATOLOGY management of alcohol use Disorder disorder in the setting of TOOLBOX Screening + Brief alcohol-associated liver Intervention disease, Hepatology seems to have made an exception. Pharmacotherapy Anti-virals **Beta blockers** Calcineurin Liver Biopsy **Behavioral** Steroids **Bile acids** inhibitors Endoscopy Therapy **Diuretics** Octreotide Immune Rifaximin Terlipressin modulators Lactulose Paracentesis

Sedarous M, Flemming JA. Clinical Liver Disease 2023

Multidisciplinary and integrated approach before and after liver transplantation for alcohol-related liver disease



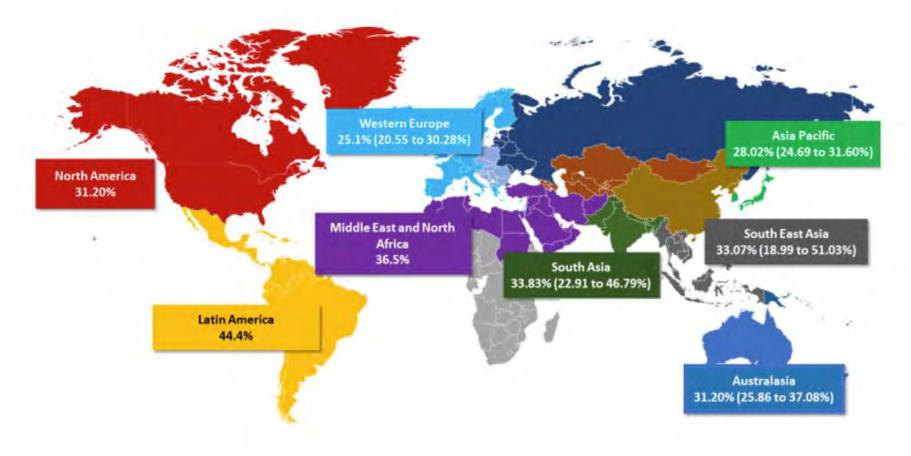
Shroff H. and Gallegher H. Clinical Therapeutics 2023 Germani G, Degré D, Moreno C, Burra P. UEGJ 2024

Shifting paradigm in management of alcohol-related hepatitis

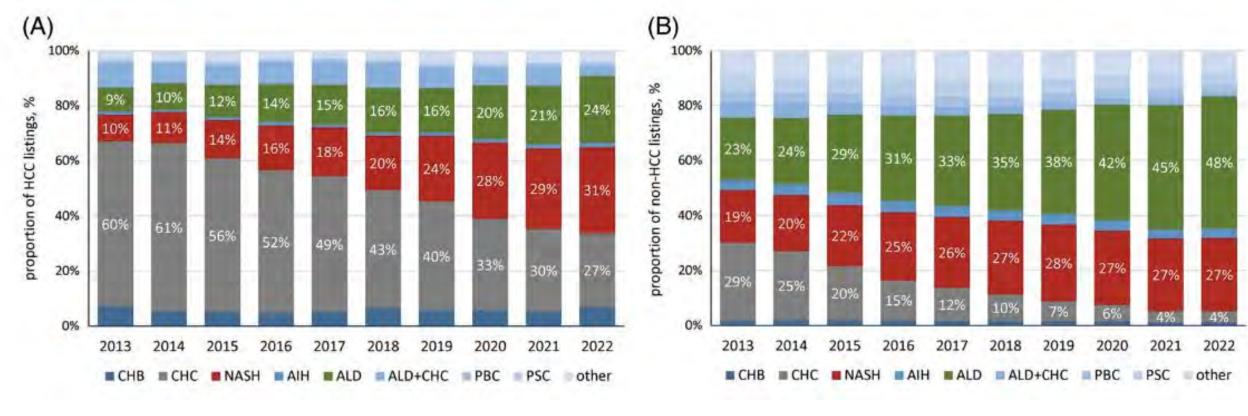
Supportive Care								
Acute/Critical care medicine Hemodynamic & respiratory support Renal replacement therapy Antibiotics	Medical Therapy							
	Glucocorticoids Prednisolone Methylprednisolone Other Therapies N-acetylcysteine	Liver Transplantation						
Hepatic decompensation care Hepatic encephalopathy Ascites Gastrointestinal bleeding		After alcohol abstinence ≥6 months sobriety	Early transplant <6 months sobriety					
Abstinence from alcohol Pharmacotherapy Psychiatric treatment Substance abuse treatment	Granulocyte colony stimulating factor Fecal microbiota transplant							

Global pooled prevalence of MASLD: 30.5%

Allen, Lazarus and Younossi J Hepatol 2023



The name chosen to replace NAFLD is metabolic dysfunction-associated steatotic liver disease (MASLD) J Hepatol 2023 The changing epidemiology of adult liver transplantation in the United States in 2013-2022 The dominance of metabolic dysfunction—associated steatotic liver disease and alcohol- associated liver disease (at listing)



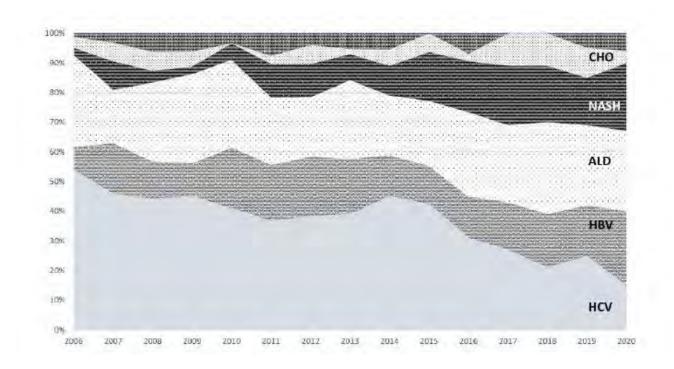
(A) Proportion of HCC
HCV 60% (2013) to 27% (2022)
MASH 10% (2013) to 31% (2022)
ALD 9% (2013) to 24% (2022)

(B) Proportion of non-HCC

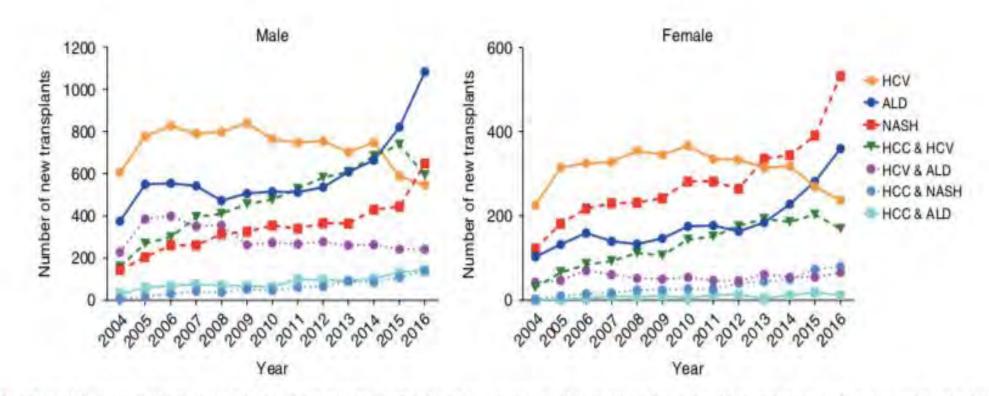
Younossi Hepatology Communications 2024

How the Waiting List Is Changing for Liver Transplantation: A Single Center Experience from Italy

- NASH patients accounted for 12% of 1491 registrations (January 2006-June 2020).
- An increasing trend over time from 2.5%
 in 2006 to 23% in 2020 was seen.
- This trend was confirmed both for patients with decompensated cirrhosis from 1.8% to 18% - and HCC - from 4% to 30%.



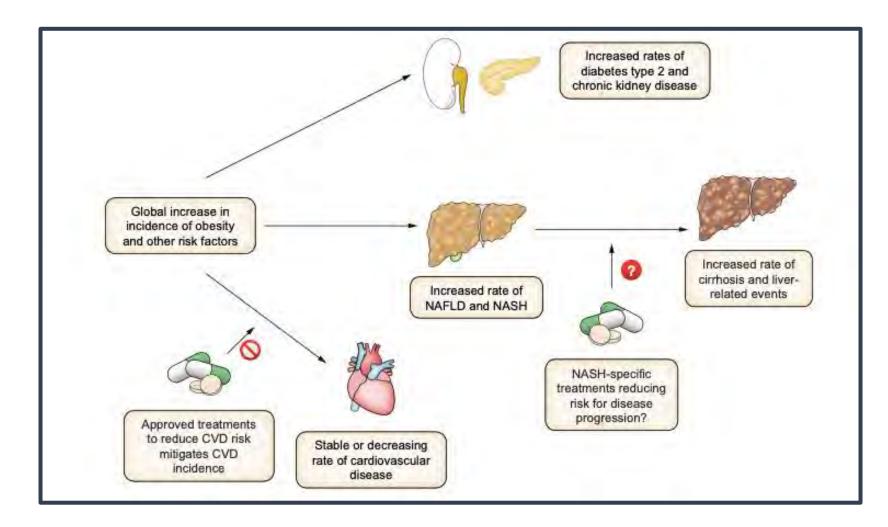
MASH leading cause of liver transplantation in U.S.



Number of liver transplants by indication and gender. Left side shows number of liver transplants by disease category in males while the right side shows this number in females. HCV hepatitis C virus, ALD alcoholic liver disease, NASH nonalcoholic steatohepatitis, HCC hepatocellular carcinoma

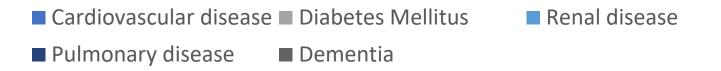
Mazen Noureddin AJG 2018

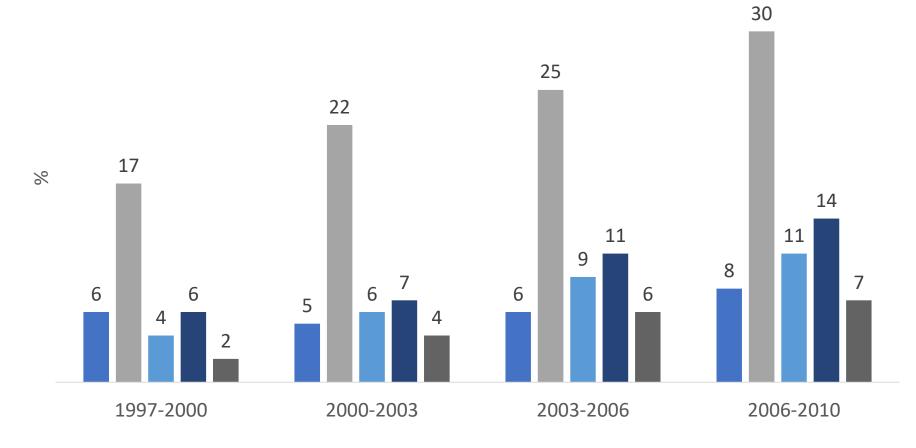
Implications of an increase in the prevalence of MASLD on clinical outcomes



Wong, Ekstedt, Grace, Wong, Hagström J Hepatol 2023

Prevalence individual comorbidity in liver transplant patients by era of transplantation

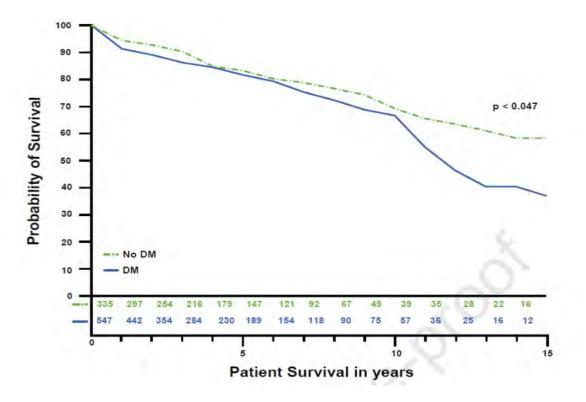




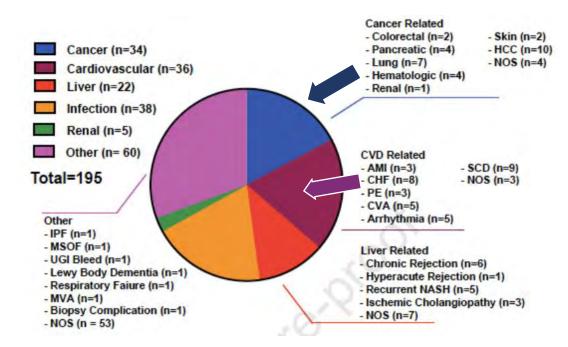
Tovikkai BMJ Open 2015

Survival in patients transplanted for NASH cirrhosis (U.S. 1997-2017)

By diabetes (DM) status before transplantation

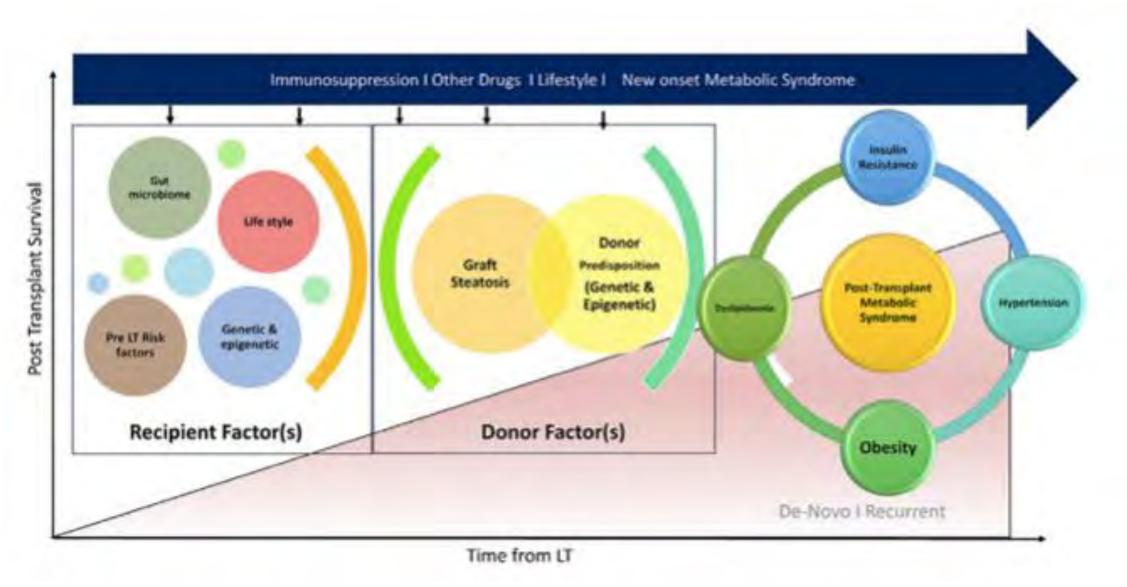


Causes of death after transplantation



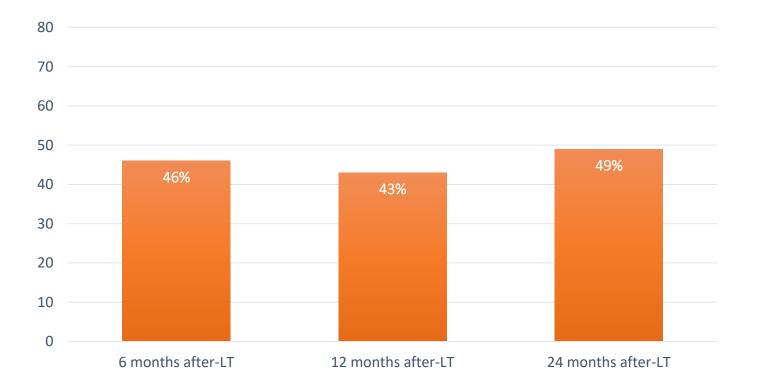
Rinella Clin Gastroenterol Hepatol 2022

Risk factors of Post-Transplant Metabolic Syndrome: pre transplant elements of both donors and recipient as well as post-transplant components of recipients



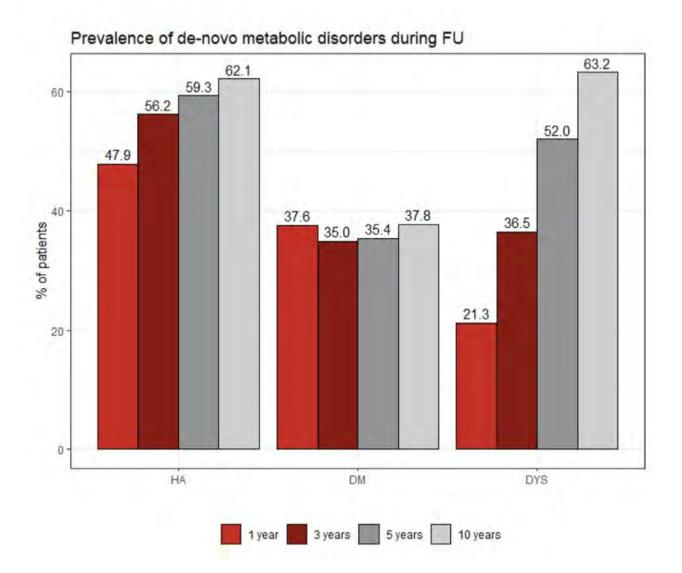
A prospective longitudinal assessment of *de novo* metabolic syndrome after liver transplantation

63 liver transplanted patients (2013-2017) with 24-month complete follow-up at Multivisceral Transplant Unit Padua Italy



Becchetti, Burra, Germani Clin Transpl 2022

MASH Continues as a Significant Burden on Metabolic Health of Liver Recipients



Kinga Czarnecka Transplantation Proceedings 2024

Immunosuppressive drugs and metabolic syndrome

DRUG	НТА	DIABETES	LIPIDS	OBESITY	METABOLIC SYNDROME
Tacrolimus					
Cyclosporine					
Corticosteroids					
Everolimus					
MMF					
Anti-IL2-R					
No/margin	al influence	Moderate	e influence	Strong influ	ience

A prospective longitudinal assessment of *de novo* metabolic syndrome after liver transplantation: risk factors of diabetes

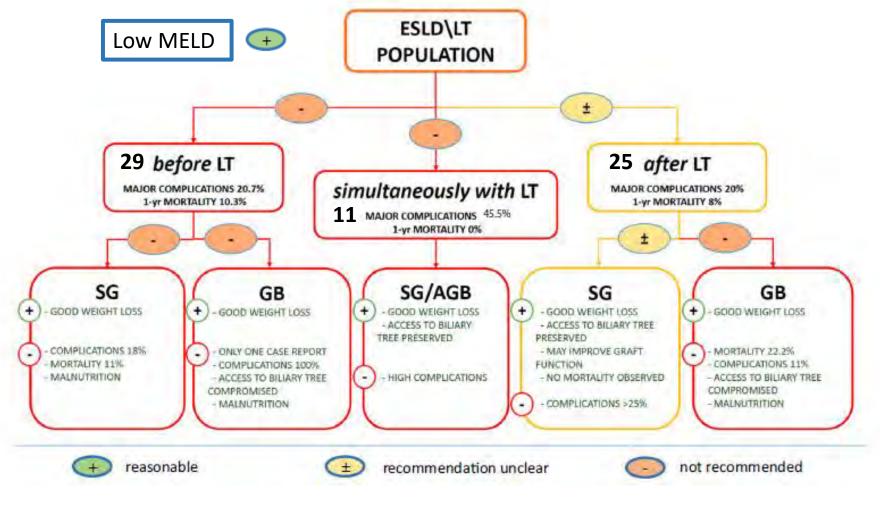
DM II after-LT	Multivariate analysis			
	HR	95% CI	p value	
Age, years	1.02	0.96-1.09	0.51	
IFG pre-LT	1.02	1.01-1.03	0.001	
DM II pre-LT	2.56	0.97-6.76	0.06	
MMF	0.18	0.04-0.87	0.03	

Life style intervention



Ratziu Transplantation 2019

Bariatric surgery in patients with severe morbid obesity

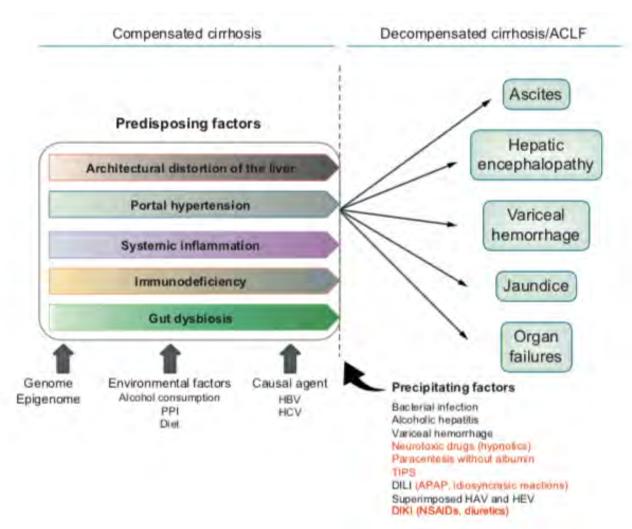


Dziodzio Obesity, 2017

ESLD: end-stage liver disease SG: Sleeve gastrectomy GB: gastric bypass AGB: adjustable gastric bandings

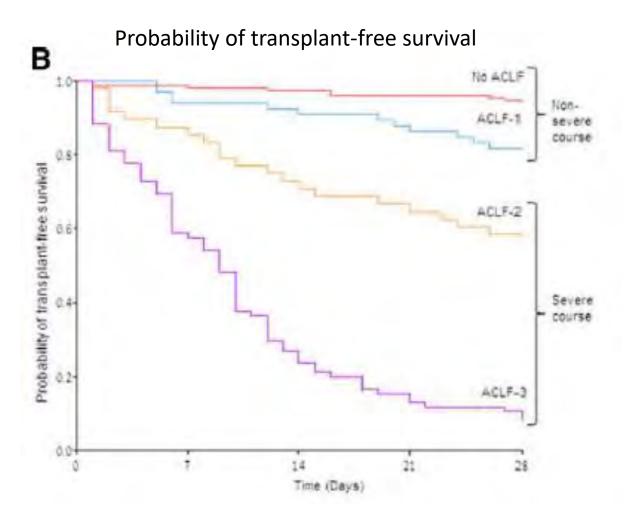
Transition to decompensation and acute-on-chronic liver failure: Role of predisposing factors and precipitating events

Thierry Gustot, Vanessa Stadlbauer, Wim Laleman, Carlo Alessandria, Mark Thursz Journal of Hepatology 2021



APAP, acetaminophen; DIKI, drug-induced kidney injury; DILI, drug-induced liver injury; PPI, proton pump inhibitor; TIPS, transjugular intrahepatic portosystemic shun

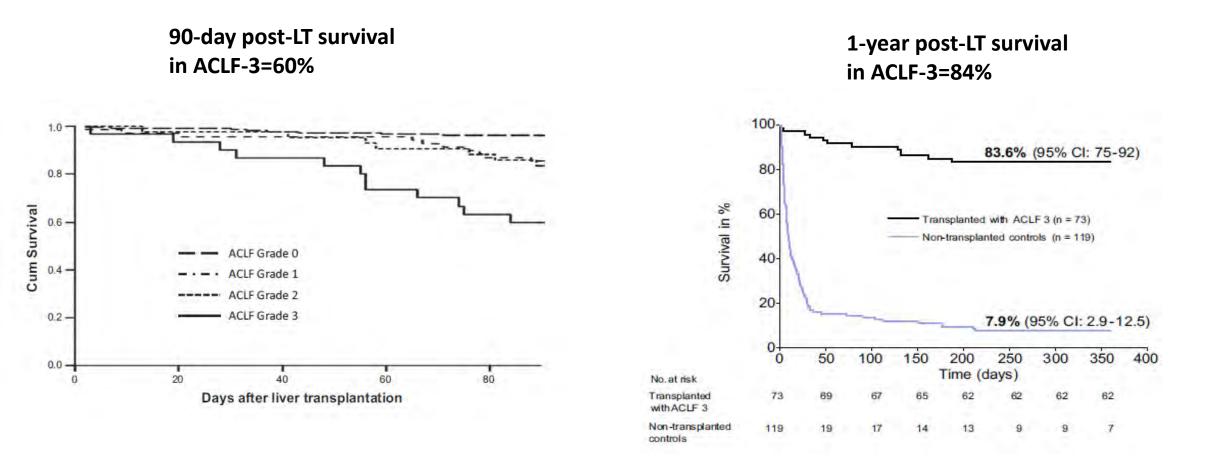
Role of liver transplantation (LT) in patients with ACLF3



Initial data from the CANONIC study revealed 1-year post-LT survival of 75% among 25 patients transplanted with ACLF, of whom 9 had ACLF-3 and none had respiratory failure.

Improvement or worsening of ACLF occur very rapidly.

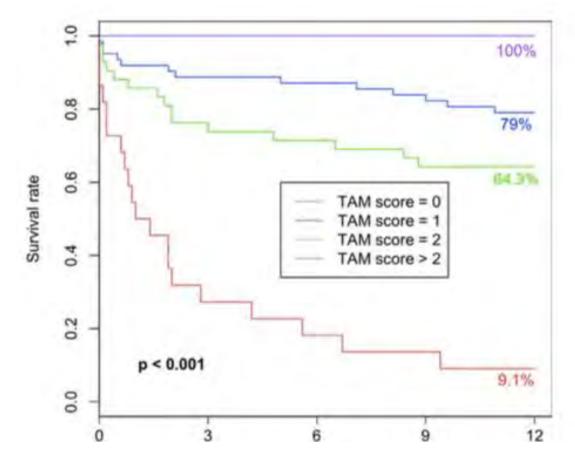
Survival after liver transplantation (LT) in patients with ACLF3



Artru J Hep 2017

Survival rate after liver transplantation in the entire cohort depending on the transplantation for ACLF-3 TAM score

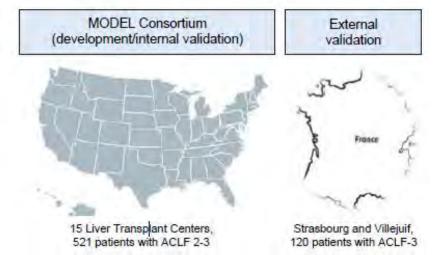
	Points
Arterial lactate level (mmol/l)	
<4	0
≥4	1
Mechanical ventilation with PaO_2/FiO_2 ratio ≤ 20	0 mm Hg
No	0
Yes	1
Age (years)	
<53	0
≥53	1
Leukocyte counts (G/I)	
>10	0
≤10	1
TAM score	= Σ



The score can help stratify post-transplant survival and identify an optimal transplantation window for patients with ACLF-3

The novel SALT-M score predicts 1-year post-transplant mortality in patients with severe acute-on-chronic liver failure

Ruben Hernaez^{1,2,3,*,#}, Constantine J. Karvellas^{4,#}, Yan Liu^{2,3}, Sophie-Caroline Sacleux^{5,6}, Saro Khemichian⁷, Lance L. Stein⁸, Kirti Shetty⁹, Christina C. Lindenmeyer¹⁰, Justin R. Boike¹¹, Douglas A. Simonetto¹², Robert S. Rahimi¹³, Prasun K. Jalal³, Manhal Izzy¹⁴, Michael S. Kriss¹⁵, Gene Y. Im¹⁶, Ming V. Lin¹⁷, Janice H. Jou¹⁸, Brett E. Fortune¹⁹, George Cholankeril³, Alexander Kuo²⁰, Nadim Mahmud²¹, Fasiha Kanwal^{1,2,3}, Faouzi Saliba⁵, Vinay Sundaram^{20,‡,†}, Thierry Artzner^{22,‡}, Rajiv Jalan^{23,24,25,‡}, for the Multi-Organ Dysfunction and Evaluation for Liver Transplantation (MODEL) Consortium⁵



Tool: logistic regression using clinically meaningful variable selection in addition to modern selection techniques. Adequate power for 5 predictors. Used median regression to estimate median length of stay using the same principles.

- ✓ Age 50+
- ✓ Diabetes mellitus
- ✓ Body mass index (continuous)
- Circulatory failure (one or 2+ inotropes)
- ✓ Respiratory failure

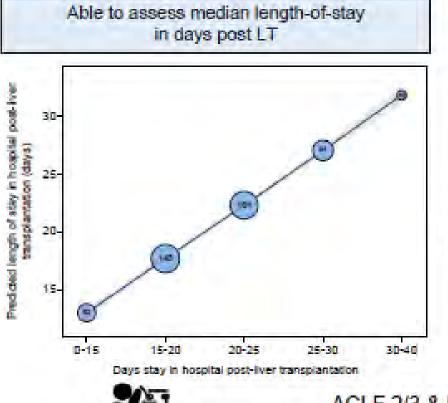
The aim was:

- to develop and externally validate a model to predict 1-year mortality after liver transplantation in patients with ACLF-grade 2 or 3
- to estimate the median length of stay after transplant

Predictors in the final model

Sundaram ACLF-LT (SALT)-Mortality score predicts 1-year mortality probability post-LT

AUROC 0.72 (development) AUROC 0.80 (external validation)



Adjusted for age, body mass index, diabetes use of inotropes, respiratory failure, prior history of MDRB, RRT and WBC at LT

- ACLF 2/3 & LT candidate?
 The Sundaram score can help in the discussions of LT in these patients

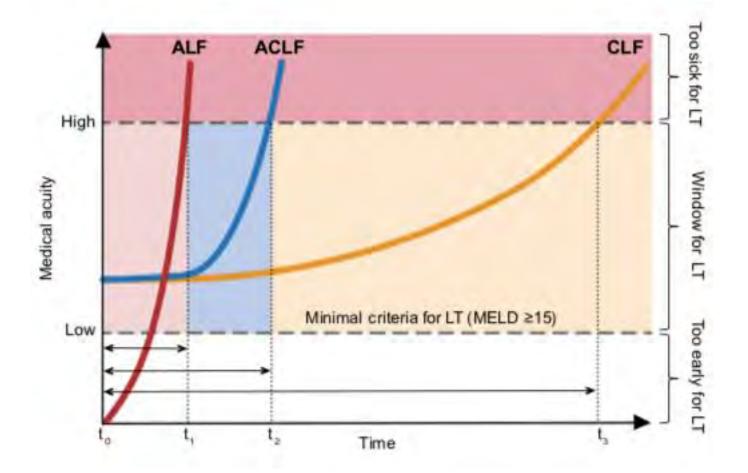
MDRB, multidrug resistant bacteria; RRT, renal replacement therapy; WBC, white blood cell count

- Age, BMI, and the presence of diabetes, respiratory failure, and/or circulatory failure predicted death within 1 year with reasonable accuracy.
- In addition, the prior presence of infection, use of renal replacement therapy, and leukocyte count at liver transplantation also influenced the median length of stay.

Impact and implications

This score can help in discussions with patients and care teams when patients are considered "too sick" for liver transplantation.

Nevertheless, the score is far from perfect and other factors, such as patient's preference and center-specific factors, need to be considered when using these tools. Principle courses of three types of liver failure (ALF, ACLF, and CLF) plotted as function of medical acuity over time



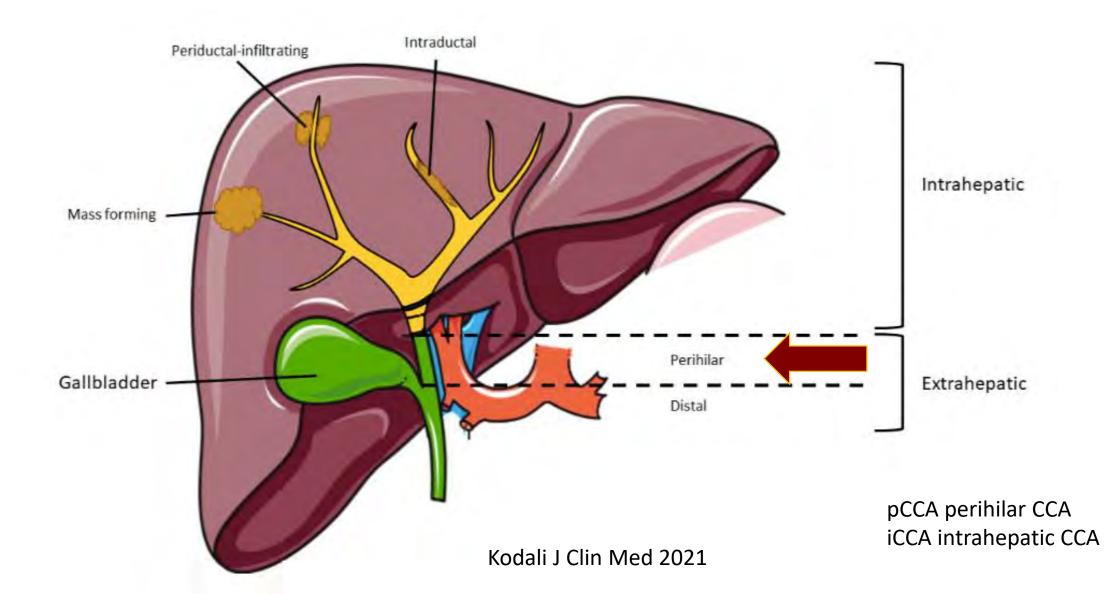
The rapid onset of sequential organ failure as it occurs in ALF and ACLF leads to a short window of opportunity for liver transplantation.

Should patients with acute-on-chronic liver failure grade 3 receive higher priority for liver transplantation?

- 62-year-old male, decompensated alcohol-associated cirrhosis, recurrent ascites and hepatic encephalopathy
- Type 2 diabetes, arterial hypertension, BMI 31 kg/m2
- Admitted to ICU, on mechanical ventilation, on norepinephrine
- MELD-Na 31
- Massive variceal bleed with hypovolemic shock
- Intubated, on renal replacement therapy, lactate 3.1 mmol/L
- ACLF-3, with 5 organ failures (liver, kidney, coagulation, circulation, and respiration)

Is it appropriate to perform liver transplantation in such a patient?

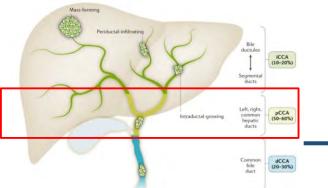
Classification of cholangiocarcinoma (CCA) by anatomic location



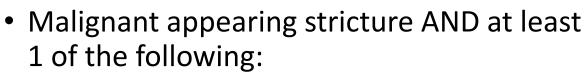
pCCA: LIVER TRANSPLANTATION

European experience



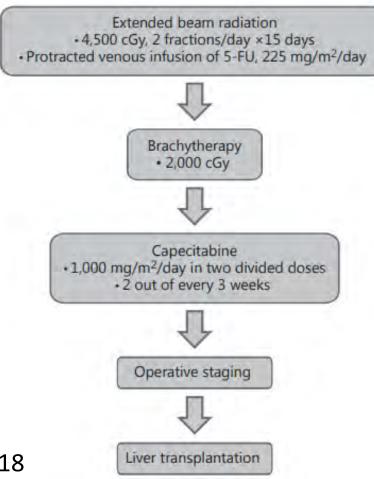


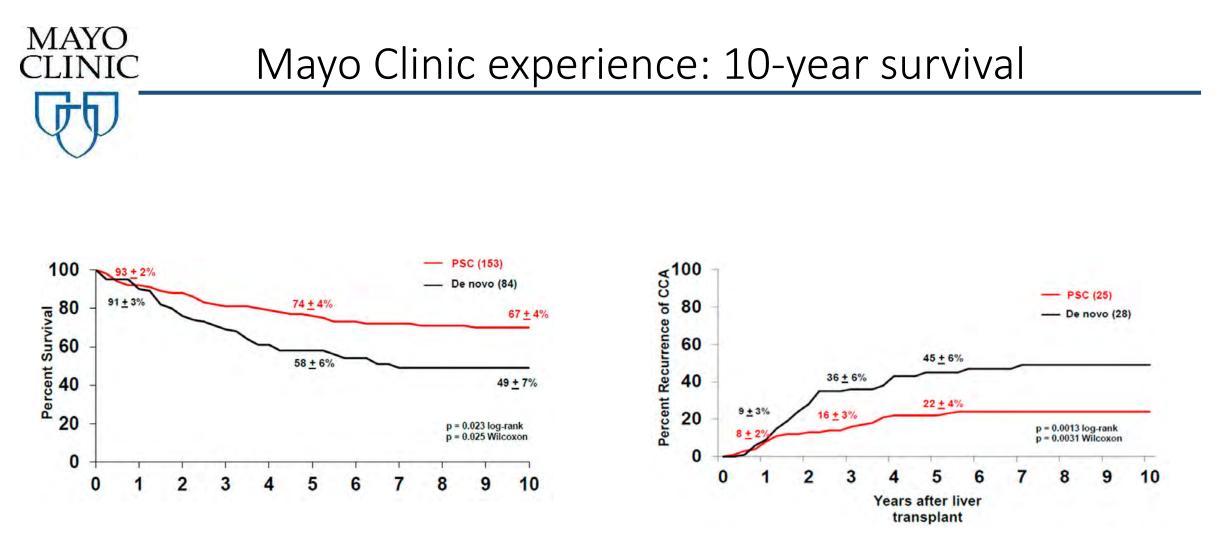
Liver transplantation for pCCA -Mayo Clinic selection criteria and treatment



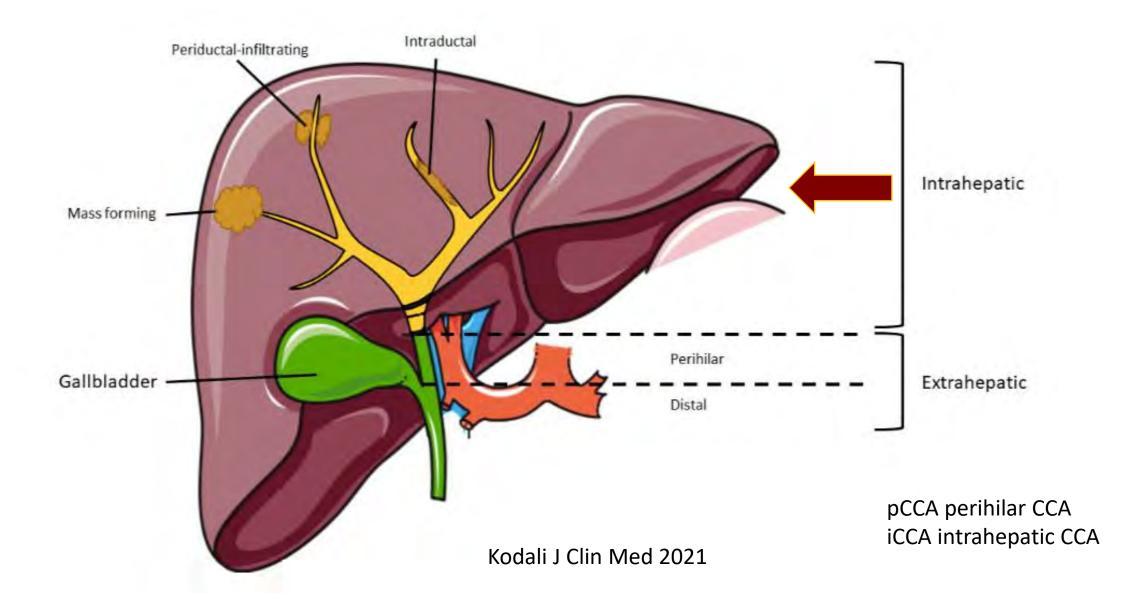
- Malignant cytology or histology
- Ca 19-9 > 130 U/mL without cholangitis
- Mass on cross-sectional imaging (radial diameter ≤ 3 cm)
- No extrahepatic disease
- Cancer located above the cystic duct
- Unresectable cancer (*de novo* CCA) or cancer arising in the context of PSC (two distinct patient populations)

Zamora-Valdes and Heimbach Gastroenterol Clin N Am 2018





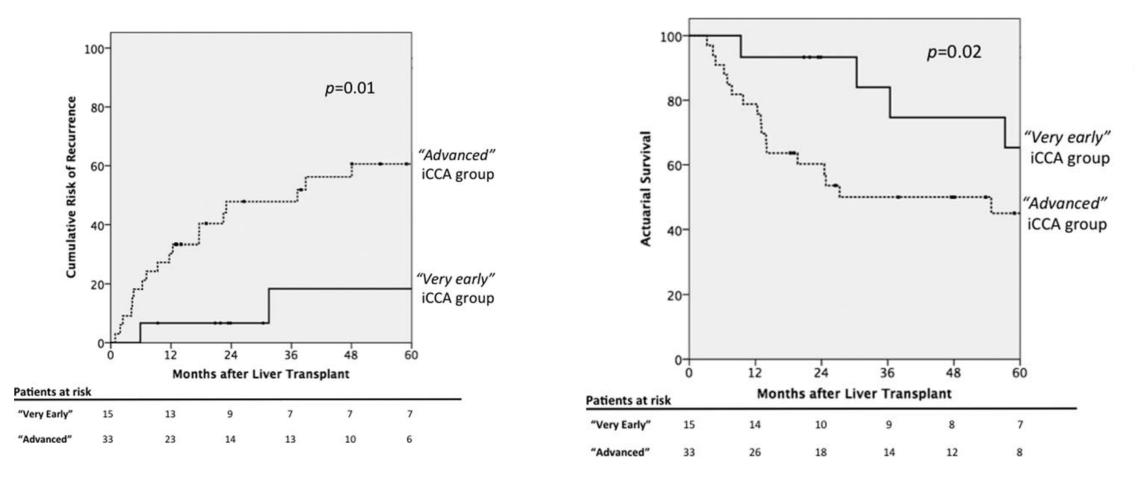
Classification of cholangiocarcinoma (CCA) by anatomic location



Liver transplantation in 48 very early iCCA (single tumor ≤ 2 cm)

5-years recurrence 18% and 5-year survival 65%

International retrospective study



Sapisochin G et al. Hepatology 2016

Liver Transplantation for Intrahepatic Cholangiocarcinoma: Ready for Prime Time?

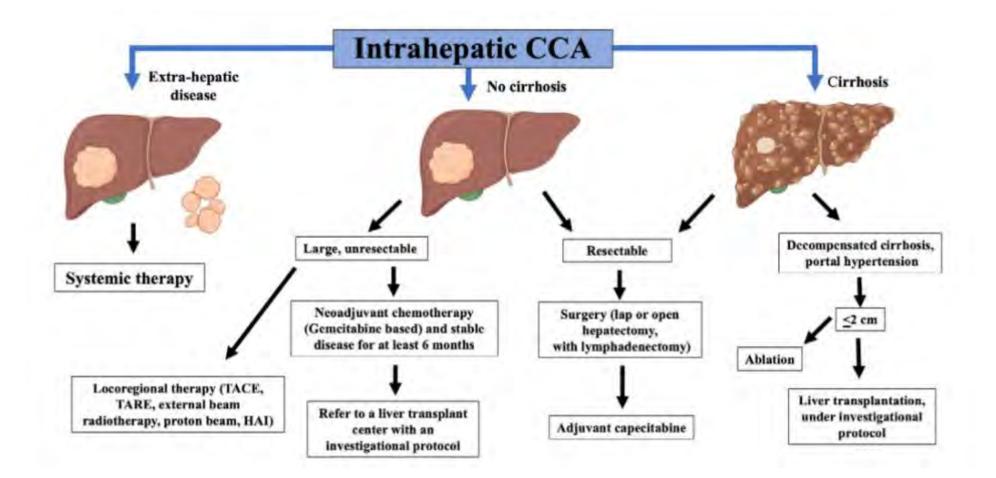
Gonzalo Sapisochin¹ | Tommy Ivanics^{1,2,3} | Julie Heimbach⁴

Recent analyses of outcomes of liver transplantation for iCC have suggested that iCC may be a potentially feasible option for highly selected patients:

- Very early disease (single tumor, ≤2 cm) with cirrhosis not candidates for liver resection.
- Locally advanced iCC, but where the extent of liver resection would be too extensive to be feasible.

Hepatology. 2022;75:455-472.

Proposed treatment approach to patients with iCC and the role of liver transplant



Updates in Surgery 2021 https://doi.org/10.1007/s13304-021-01064-w

LETTER TO THE EDITOR



Liver transplantation for unresectable intrahepatic cholangiocarcinoma: an Italian experience

Salvatore Gruttadauria^{1,2} · Marco Barbara³ · Rosa Liotta⁴

14 liver transplantations for iCCA.

12/14 cases incidentally diagnosed on pathologic examination

11/12 on cirrhotic livers

9/12 mixed form of iCCA and HCC

2/14 locally advanced unresectable iCCA, neoadjuvant treatment, 1–3 months of follow-up, and then liver transplant within 3 months

Overall survival for the incidentally diagnosed group: 69.4% at 5 years

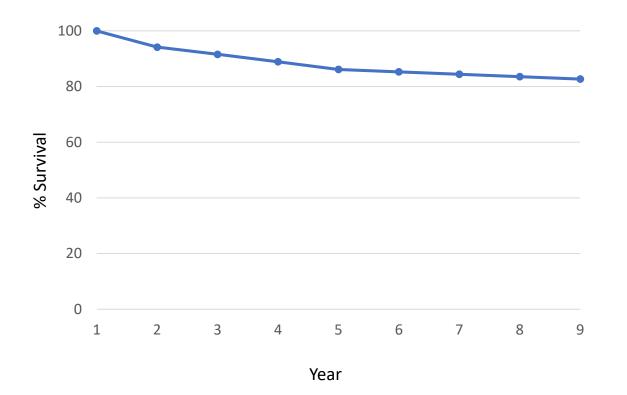
2 non-incidental cases are alive after 19 and 2 months



Italian Association for the Study of the Liver (AISF) – Permanent Transplant Commission (PTC)

Nationwide survey of liver transplantation for Primary Sclerosing Cholangitis in Italy

Overall patient survival

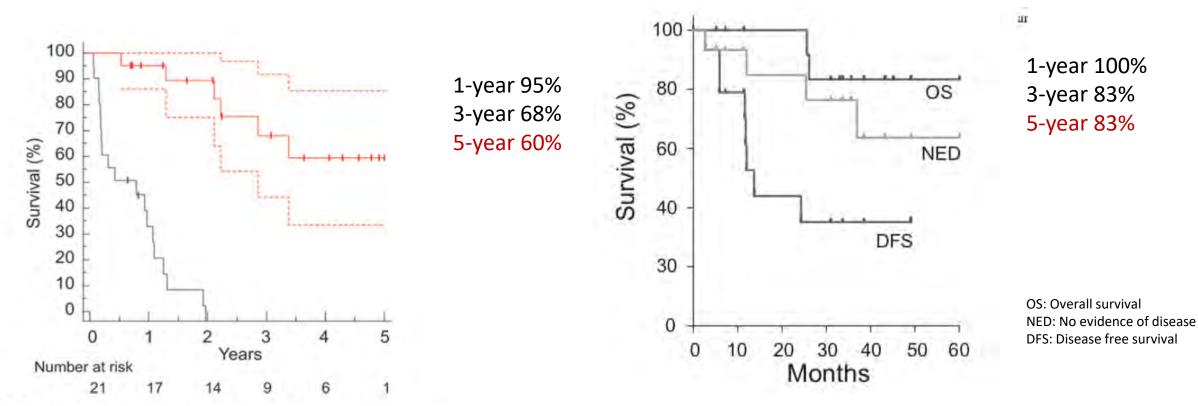


81/411 (20%) PSC recurrence (rPSC) 66/411 (16%) mortality 24 (36%) <1 year Surgical complications (50%) Infections (25%) 33 (50%) 1-5 years rPSC (36%) CCA recurrence (21%) 9 (14%) >5 years Colon cancer (60%) rPSC (40%)

Morelli, Burra et al DLD 2023

Survival Following Liver Transplantation for Patients With Nonresectable Liver-only Colorectal Metastases

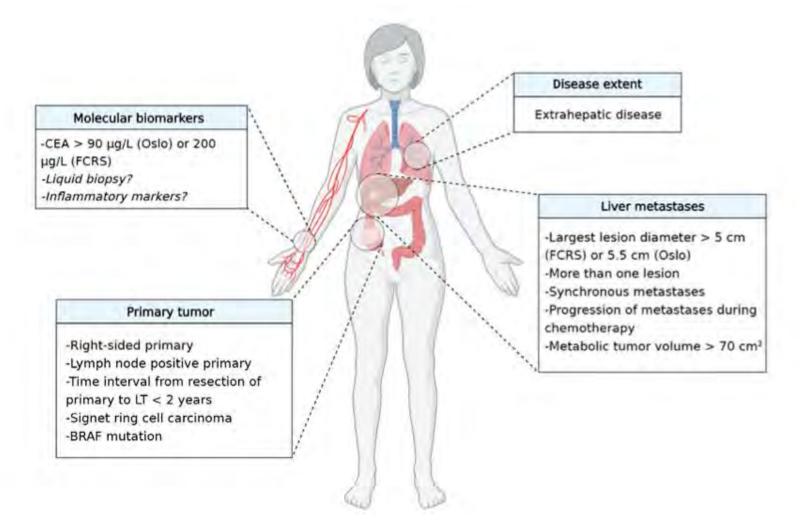
Liver transplantation in 21 cases provided an overall survival of 60% in SECA-I study.



15 patients included in the SECA-II study had better prognostic factors than the previous SECA-I study.

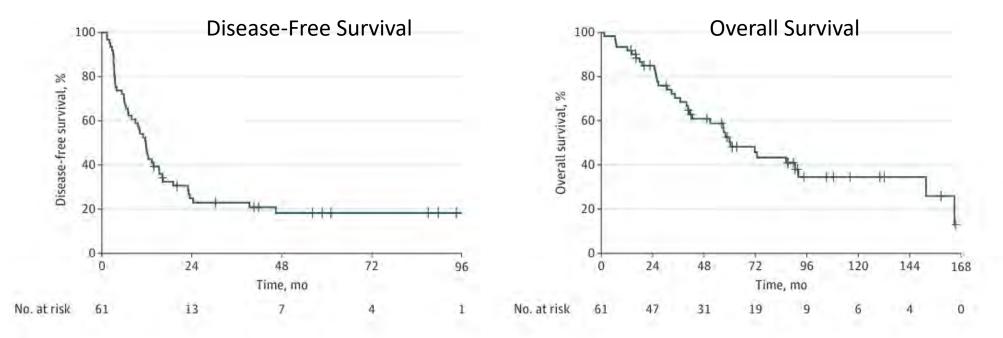
Hagness, Annals of Surgery, 2013; Dueland Ann Surg 2020

Established and potential risk factors associated with poor prognosis after liver transplantation for colorectal liver metastases



Maspero & Mazzaferro Cancers 2023

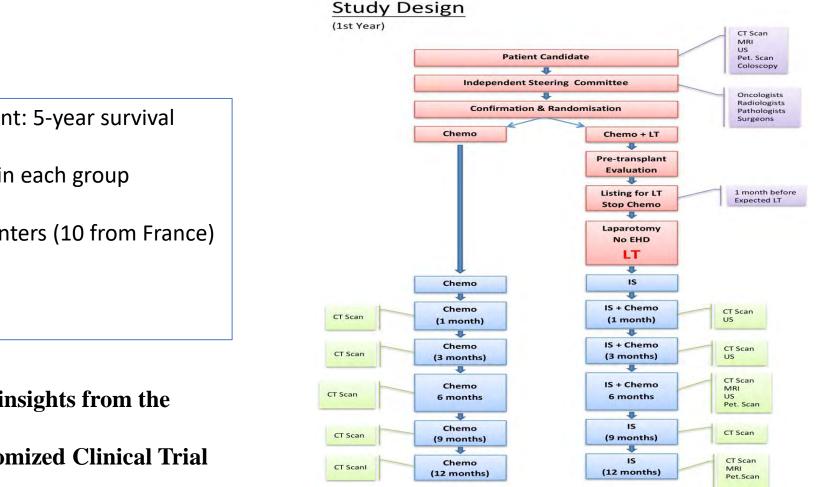
Long-Term Survival, Prognostic Factors, and Selection of 61 Patients With Colorectal Cancer for Liver Transplant



Some of the negative predictive factors

- largest tumor size greater than 5.5 cm
- progressive disease while receiving chemotherapy
- plasma carcinoembryonic antigen values greater than 80 $\mu\text{g/L}$
- 9 or more liver lesions

TRANSMET **European Randomised Multicentric Trial:** Liver Transplantation vs Chemotherapy in patients with liver metastases from colorectal cancer



- Primary End Point: 5-year survival •
- 80 patients, 40 in each group ۲
- 17 European centers (10 from France) •

Preliminary insights from the

TransMet Randomized Clinical Trial

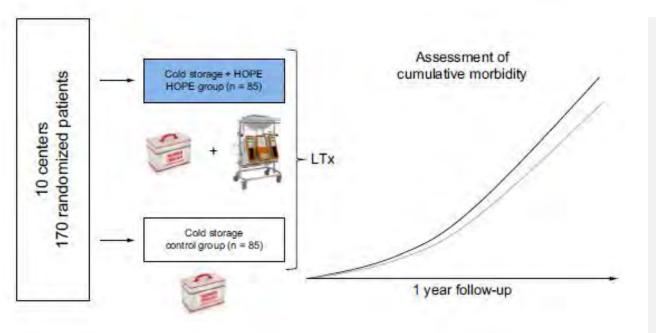
2024 Submitted

Courtesy from Rene' Adam

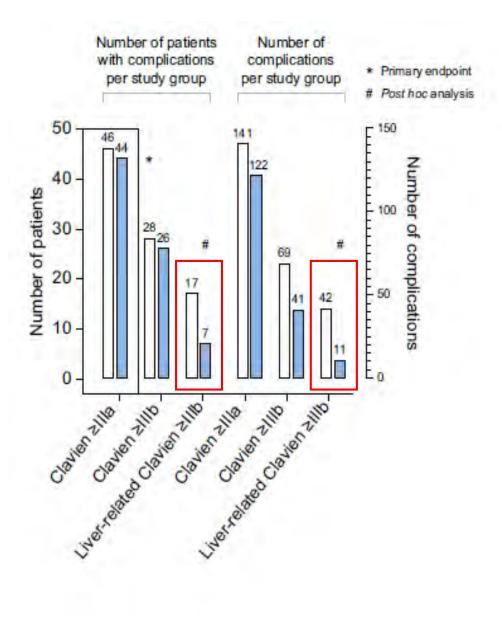
A multicenter randomized-controlled trial of hypothermic oxygenated perfusion (HOPE) for human liver grafts before transplantation

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Journal of Hepatology, April 2023. vol. 78 | 783-793



- Randomized controlled trial, assigning livers donated after brain death for liver transplantation.
- Livers were either conventionally cold stored (control group), or cold stored and subsequently treated by 1-2 h hypothermic oxygenated perfusion (HOPE) before implantation (HOPE group).
- The primary endpoint was the occurrence of at least one post-transplant complication per patient, graded by the Clavien score of ≥III, within 1-year after transplant.

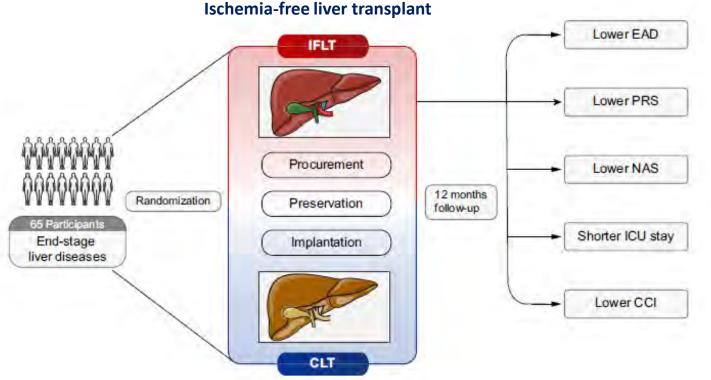


- The number of patients with at least one Clavien ≥ III complication was not significantly different between groups [46/85 (54.1%) in the control group and 44/85 (51.8%) in the HOPE group].
- Severe post-transplant complications (Clavien grade IIIb or more), occurred less frequently in the HOPE-group.
- Overall, it was reported a 3.7-fold lower number of liver-related Clavien ≥ IIIb complications per patient in the HOPE-group.

A randomized-controlled trial of ischemia-free liver transplantation for end-stage liver disease

Zhiyong Guo^{1,2,3,4,*,†}, **Qiang Zhao**^{1,2,3,†}, **Zehua Jia**^{1,2,3,†}, **Changjun Huang**^{1,2,3,†}, Dongping Wang^{1,2,3}, Weiqiang Ju^{1,2,3}, Jian Zhang⁵, Lu Yang⁶, Shanzhou Huang^{1,2,3}, Maogen Chen^{1,2,3}, Xiaofeng Zhu^{1,2,3}, Anbin Hu^{1,2,3}, Yi Ma^{1,2,3}, Linwei Wu^{1,2,3}, Yinghua Chen^{1,2,3}, Ming Han^{1,2,3}, Yunhua Tang^{1,2,3}, Guodong Wang^{1,2,3}, Linhe Wang^{1,2,3}, Lifen Li⁷, Wei Xiong⁶, Zhiheng Zhang^{1,2,3}, Yuekun Shen⁶, Zhaoxia Tang⁷, Caihui Zhu^{1,2,3}, Xiaoxiang Chen⁶, Xiaoguang Hu⁷, Yiwen Guo^{1,2,3}, Honghui Chen^{1,2,3}, Yihao Ma^{1,2,3}, Tao Zhang^{1,2,3}, Shunwei Huang⁷, Ping Zeng^{1,2,3}, Simei Lai^{1,2,3}, Tielong Wang^{1,2,3}, Zhitao Chen^{1,2,3}, Jinlong Gong^{1,2,3}, Jia Yu^{1,2,3}, Canhui Sun⁸, Chang Li⁸, Haiyi Tan⁸, Yao Liu^{1,2,3}, Yuqi Dong^{1,2,3}, Chengjun Sun^{1,2,3}, Bing Liao⁹, Jun Ren¹⁰, Zhenhai Zhou¹⁰, Schlegel Andrea¹¹, Nashan Bjöm¹², Changjie Cai⁷, Fengqiu Gong¹³, Jian Rong¹⁴, Wenqi Huang⁶, Xiangdong Guan⁷, Piere-Alain Clavien¹⁵, Tullius G. Stefan¹⁶, Jiefu Huang¹, Xiaoshun He^{1,2,3,*}

Journal of Hepatology, August 2023. vol. 79 | 394-402



Conventional liver transplant

Ischemia-free organ transplantation is a novel approach designed to avoid ischemiareperfusion injury, with the potential to improve outcomes

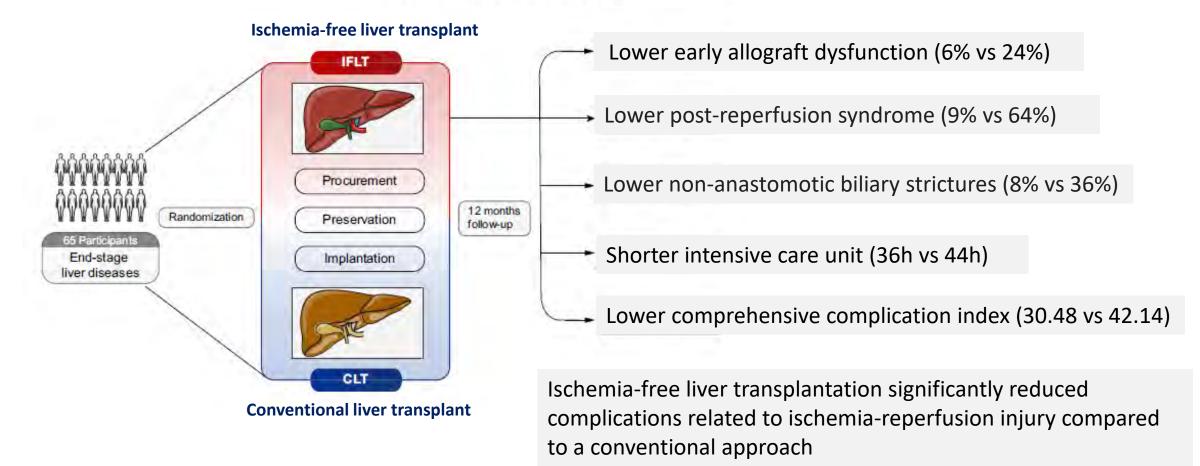
Randomized-controlled clinical trial

Recipients of livers from donors after brain death were assigned to receive an ischemiafree (32 cases) or a conventional transplant (33 cases)

A randomized-controlled trial of ischemia-free liver transplantation for end-stage liver disease

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Journal of Hepatology, August 2023. vol. 79 | 394-402

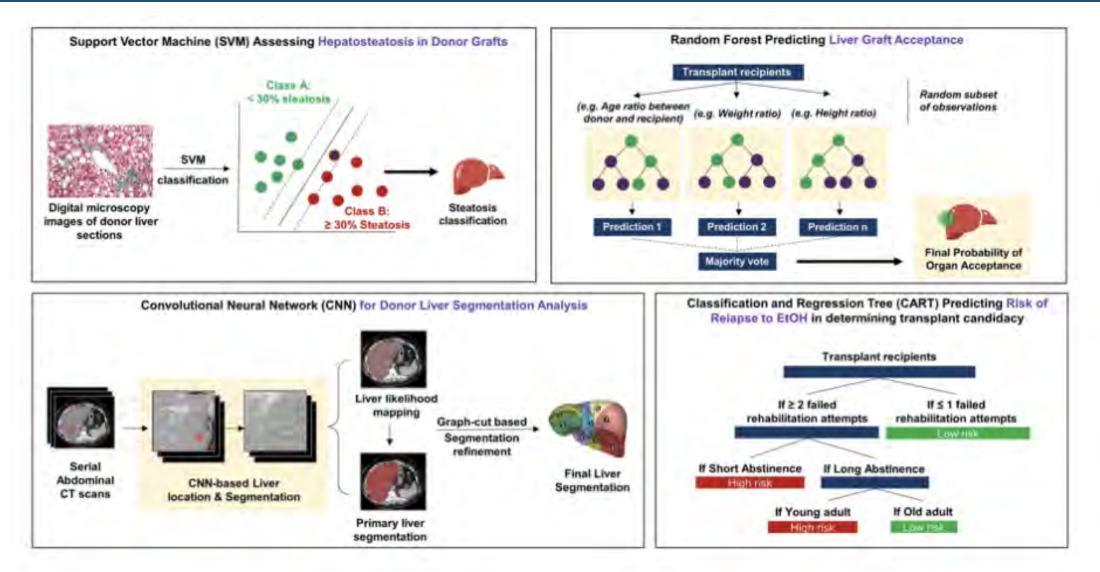


Impact and implications

Ischemia-free liver transplantation is a novel approach of transplanting donor livers without interruption of blood supply and avoid graft ischemia reperfusion injury.

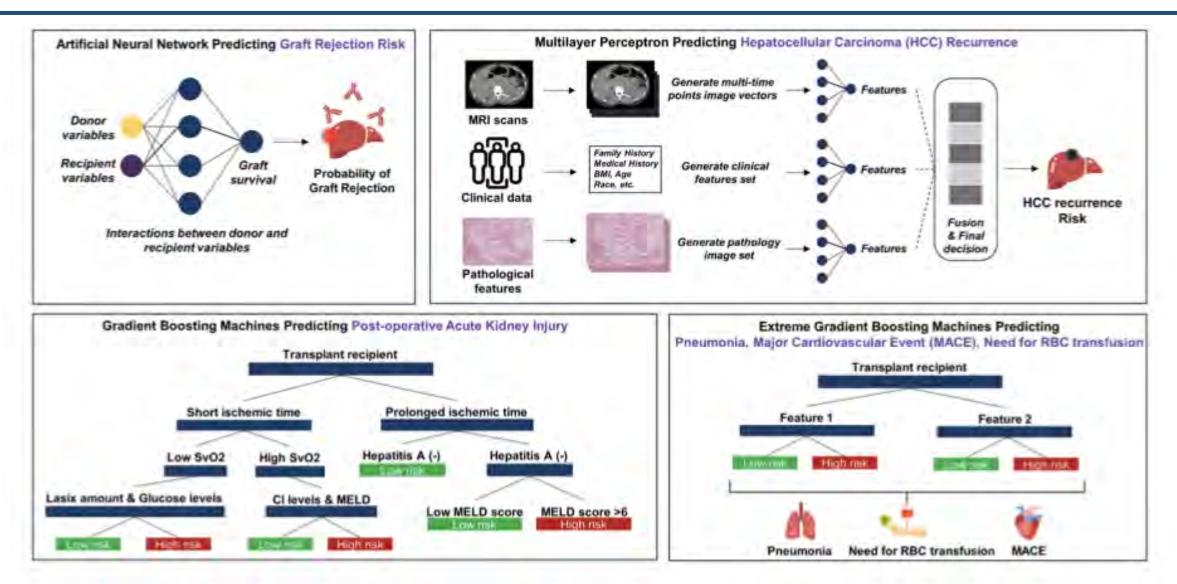
Journal of Hepatology, August 2023. vol. 79 | 394-402

Summary of machine learning applications in the pre-liver transplantation setting



Jason Tran · Divya Sharma· Neta Gotlieb · Wei Xu · Mamatha Bhat Hepatology International 2022

Summary of machine learning applications in the post-liver transplantation setting



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Take home messages

Liver transplantation is a constantly evolving discipline.

What may have been a contraindication in the past is now accepted as an indication in selected cases.

The rigor of research in transplant oncology will only tell us in the medium to long term whether the therapeutic choice was correct.

Future innovations must always take into consideration what patients expect.



Padua, Italy, Multivisceral Transplant Unit

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