



Baylor
College of
Medicine

35 year old male with Severe Alcohol Hepatitis with MELD 40

Management and Role of Liver Transplantation

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Disclosures

No disclosures

Learning Objectives

- Understand criteria for diagnosis and severity for alcohol-associated hepatitis
- Learn current and emerging therapies for treatment of severe AH
- Understand the role of liver transplantation for severe AH and current challenges faced by our transplant community

- 35 year-old male with no past medical history presenting to ER with 2-week history of sudden new onset jaundice, ascites, confusion.
- Lost his job 1 year ago and drank heavily since, averaging 12 pack of beer daily since then.
- **Physical exam:** BP 105/65 HR 87 RR 16
- Jaundice, icterus, ascitic fluid shift, 2 + LE edema, positive asterixis, awake alert oriented to person and place

Na+	Cl-	BUN
125	97	16
K+	HCO3-	Cr
3.6	22	2.0

Ca 2+	AST	INR
	132	
Protein	ALT	3.9
4.9	47	
Albumin	Alk Phos	
2.9	210	
Bilirubin		
19.4		

Hgb		
10.4		
WBC	Hct	Plt
13.4	31	124

Dialysis at least twice in the past week Or CVVHD for ≥24 hours in the past week	<input checked="" type="radio"/> No	<input type="radio"/> Yes
Creatinine Cr >4.0 mg/dL is automatically assigned a value of 4.0	<input type="text" value="2.0"/>	mg/dL ↔
Bilirubin	<input type="text" value="19.4"/>	mg/dL ↔
INR	<input type="text" value="3.9"/>	
Sodium	<input type="text" value="125"/>	mEq/L ↔

40 points	71.3%
MELD Score (2016)*	Estimated 3-Month Mortality



Alcohol-associated Liver Disease – Pandemic adding fuel to the fire

GENERAL POPULATION

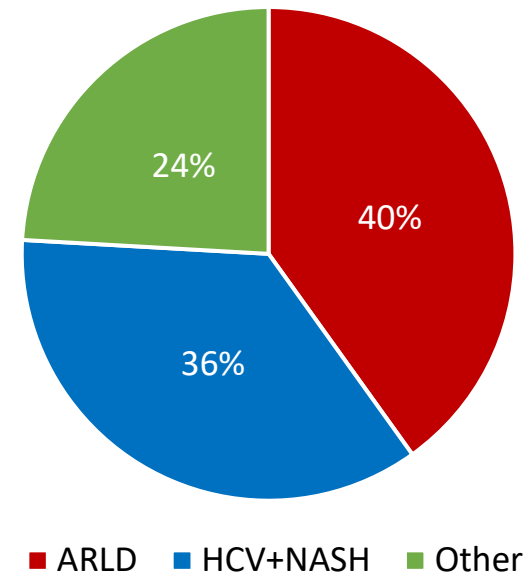
- Prevalence of binge drinking *increased* by 33% from prior.
- Healthcare utilization for ALD *increased* by 40% during pandemic
- Estimated impact of one-year increased alcohol use during pandemic by 2040:

Additional ALD-related

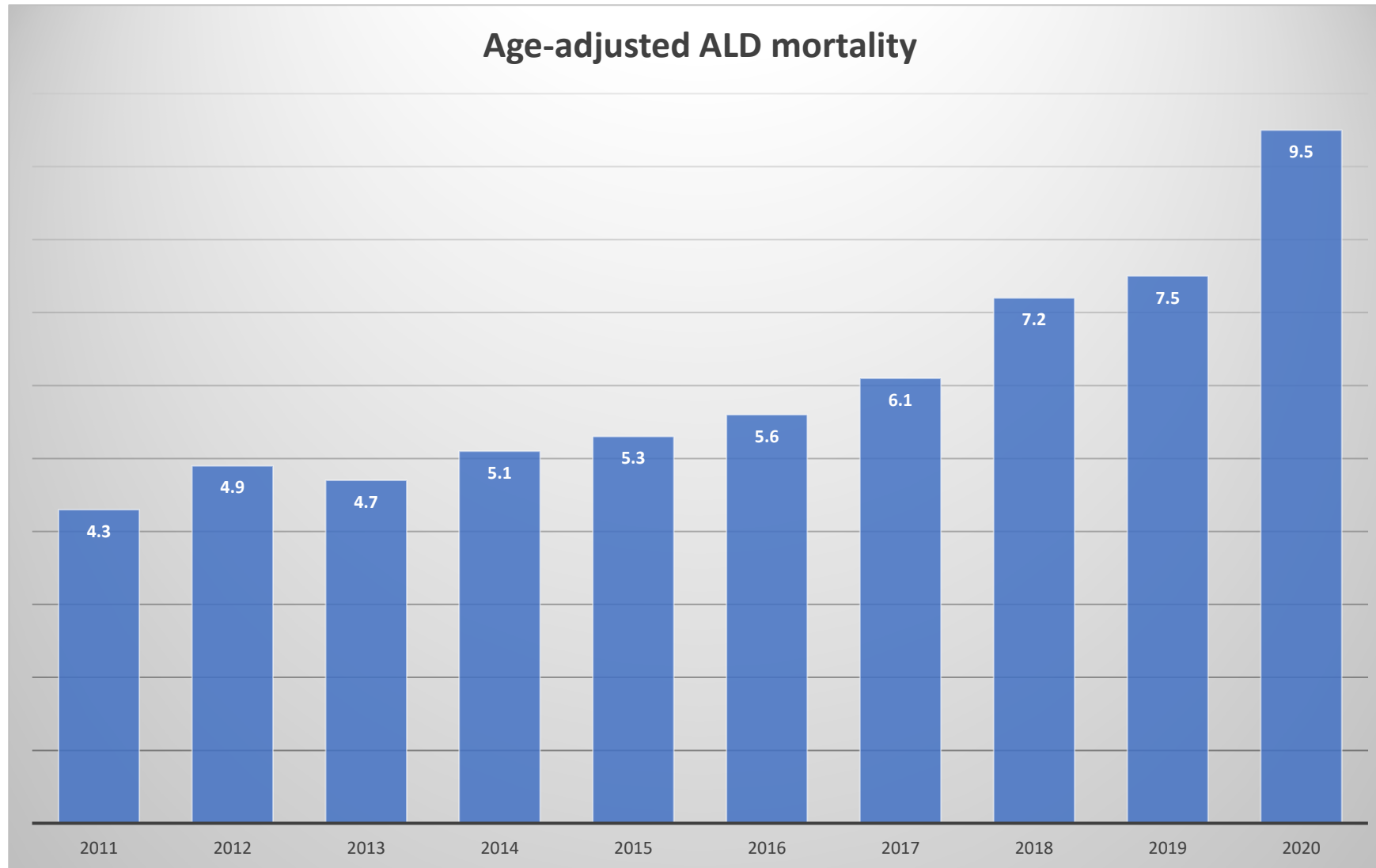
+ 8,000 deaths
+ 18,700 with decompensation
+ 1,000 new HCC cases

LIVER TRANSPLANTATION

- Regards to liver transplant, ALD (40%) > HCV (12%) and NASH (23%) combined.
- Nearly half of ALD patients listed for liver transplant MELD-Na ≥ 30
- **SAH listing diagnosis increased by 56%**



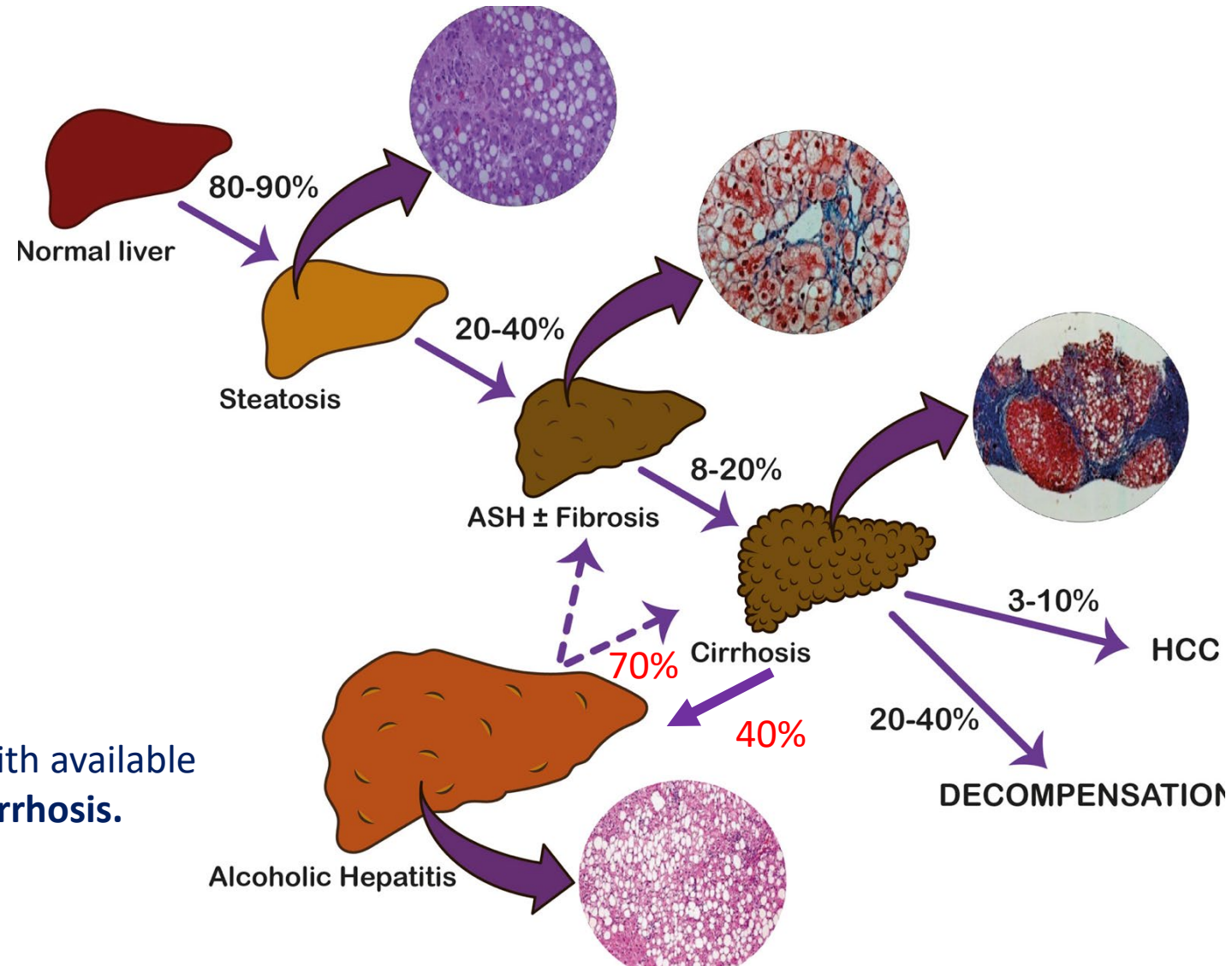
Epidemiology – ALD Mortality trends in Tennessee



**21% increase in
ALD deaths in 2020**

**120% increase since
2011**

Natural History of ALD



ACCELERATE-AH trial: 146 patients with available explant histology records, **96% had cirrhosis.**

Management of AH: Definition and diagnosis

- **Clinical**

- Recent jaundice ± other signs of liver decompensation in patients with ongoing alcohol abuse
 - Cardinal sign is **onset of progressive jaundice**, often associated with fever, malaise, weight loss and malnutrition
 - Alcohol use > 2 drinks/day in females and > 3 drinks/day in men for at least 6 months .
 - Onset of jaundice within 60 days of last drink

- **Histological**

- Steatohepatitis[†]

- **Laboratory**

- Neutrophilia
- Hyperbilirubinemia (>3 ng/dL)
- AST >2 x ULN and AST/ALT ratio typically greater than 1.5–2.0, with AST > 50
- **Severe AH:** prolonged PT, hypoalbuminemia, and decreased platelet count

*Liver decompensation includes ascites and/or encephalopathy

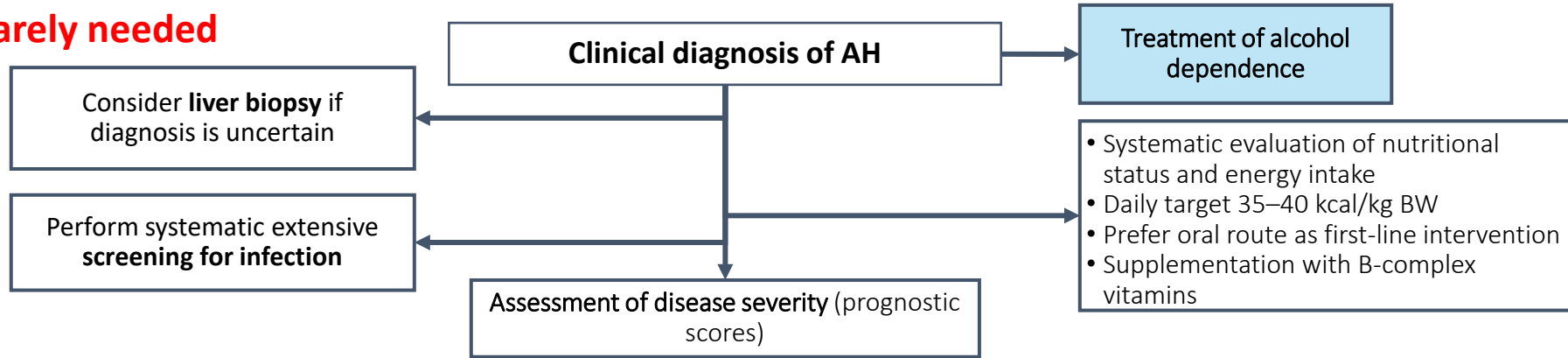
[†]Defined histologically by steatosis, hepatocyte ballooning, and an inflammatory infiltrate with polymorphonuclear neutrophils

EASL CPG ALD. J Hepatol 2018.

AASLD ALD. Hepatology 20

Management of AH: Treatment algorithm

Liver Biopsy rarely needed



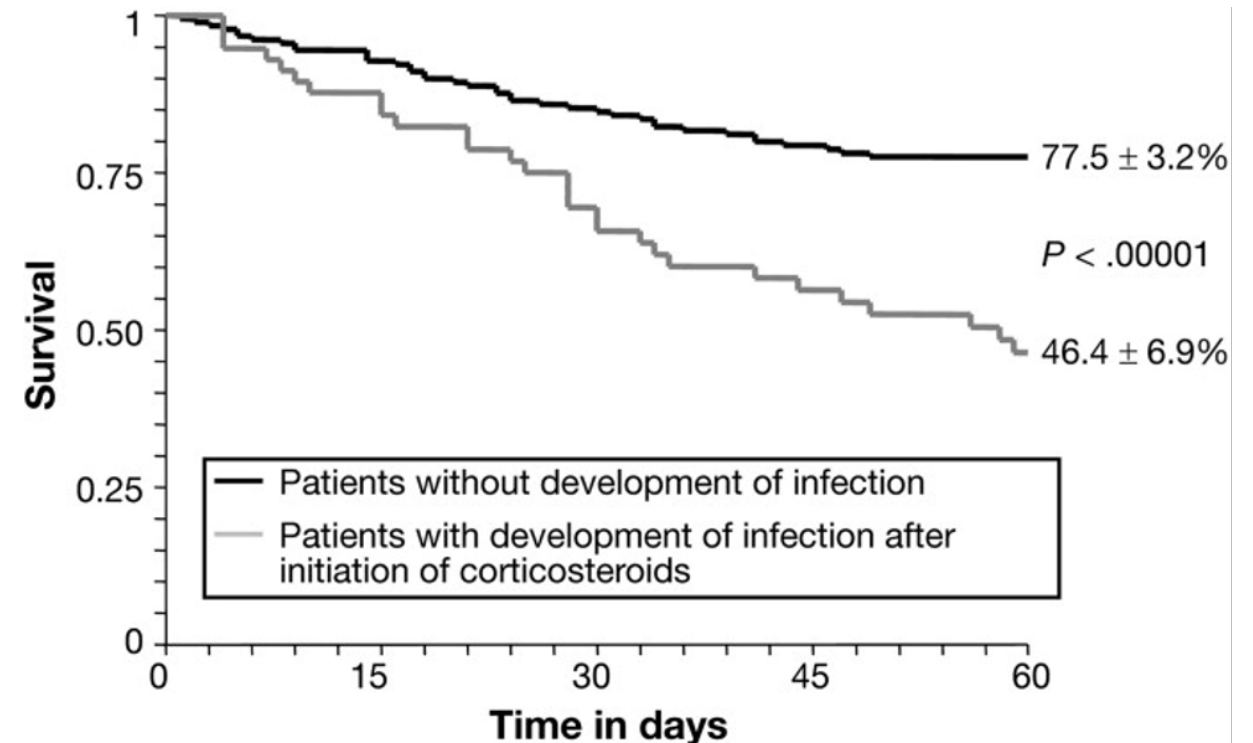
65% will get infection in 90 days

steroid AH group: 50% pulmonary infections

No steroids AH: 50% SBP

25% will die from infection

- 25.6% of patients had infections identified at admission
- 23.7% developed infection after treatment with steroids. Patients infected after treatment with corticosteroids had significantly lower 2-month survival.



Management of AH: Evaluation of severity

- Different prognostic models aim to identify patients at high risk of early death
 - Often incorporate the same variables and have similar efficacy in predicting short-term survival
- Lille model can predict pattern of response to corticosteroid treatment
 - Based on pre-treatment data plus the response of serum bilirubin

Score	Bilirubin	PT/INR	Creatinine/ urea	Leucocytes	Age	Albumin	Change in bilirubin (Day 0 to 7)
Maddrey DF*	+	+	-	-	-	-	-
MELD	+	+	+	-	-	-	-
GAHS	+	+	+	+	+	-	-
ABIC	+	+	+	-	+	+	-
Lille	+	+	+	-	+	+	+

* Modified version (mDF) cut-off value of 32 or MELD > 20 identifies patients with severe AH and is usually the threshold used for initiating specific therapy
EASL CPG ALD. J Hepatol 2018

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Score	Bilirubin	PT/INR	Creatinine/ urea	Leucocytes	Age	Albumin	Change in bilirubin (Day 0 to 7)
Maddrey DF*	First score and still widely used						
MELD	+	+	+	-	-	-	-
GAHS	+	+	+	+	+	-	-
ABIC	+	+	+	-	+	+	-
Lille	+	+	+	-	+	+	+

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Maddrey DF*	+	+	-	-	-	-	-
MELD	Score >20: high risk of 90-day mortality						
GAHS	+	+	+	+	+	-	-
ABIC	+	+	+	-	+	+	-
Lille	+	+	+	-	+	+	+

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Maddrey DF*	+	+	-	-	-	-	-
MELD	+	+	+	-	-	-	-
GAHS	Score ≥ 9 + mDF ≥ 32 : poor prognosis and survival benefit with corticosteroids						
ABIC	+	+	+	-	+	+	-
Lille	+	+	+	-	+	+	+

Management of AH: Evaluation of severity

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MELD	+	+	+	-	-	-	-
GAHS	+	+	+	+	+	-	-
ABIC	Classification according to low, medium, and high risk of death at 90 days						
Lille	+	+	+	-	+	+	+

Management of AH: Evaluation of severity

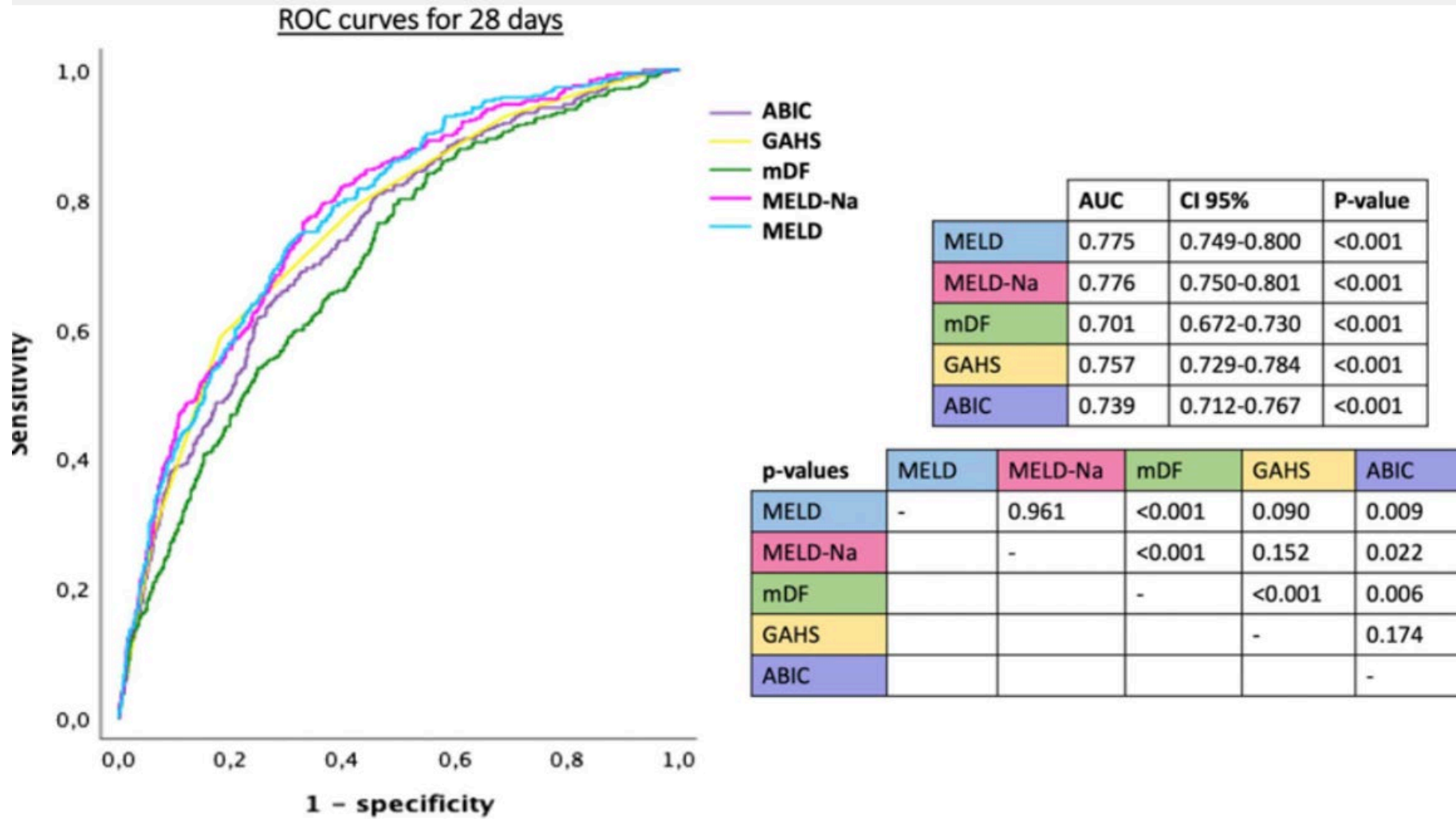


- Different prognostic models aim to identify patients at high risk of early death
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MELD	+	+	+	-	-	-	-
GAHS	+	+	+	+	+	-	-
ABIC	+	+	+	-	+	+	-
Lille	Score is 0–1; a score of ≥ 0.45 indicates non-response to corticosteroids [†]						

Comparison of Prognostic Scores in SAH

2,581 patients with SAH



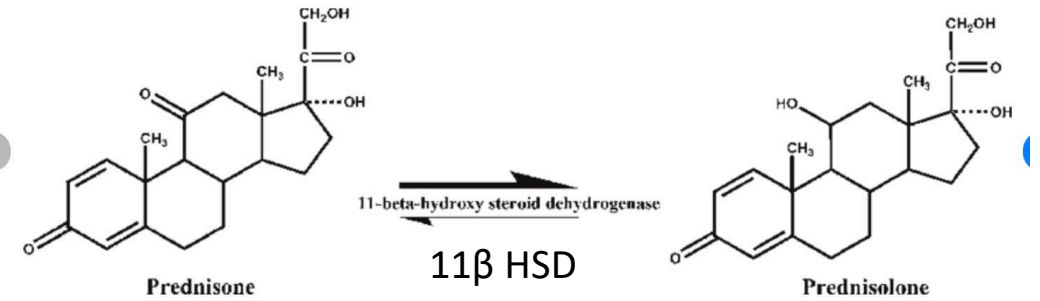
Management of AH: Why corticosteroids?

- Steroids were first used in 1950 to treat cirrhosis, with the aim of decreasing fibrosis and inflammation.
- 9 patients with cirrhosis were treated with adrenal cortex extract, and **all 9 improved and survived** with no evidence of liver dysfunction at the one-year follow-up. First study to show the potential benefits of using steroids in the treatment of cirrhosis.
- 1960, RCT in 97 patients with cirrhosis who received prednisolone, testosterone, or no treatment.

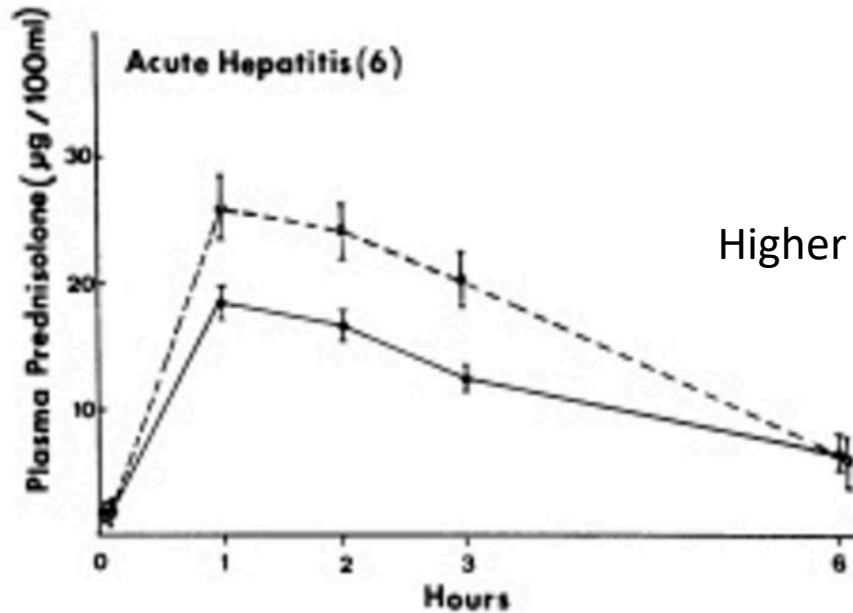
TABLE II—MORTALITIES AND IMMEDIATE CAUSE OF DEATH IN THE THREE TRIAL SERIES

	Control series (27 cases)	Prednisolone series (27 cases)	Testosterone series (26 cases)
Death in hepatic coma	12	3	6
Death from hæmatemesis	2	1	0
Other deaths	1	3	2
Total	15	7	8

Management of AH: Why prednisolone?



- Prednisone to Prednisolone: First pass activation in liver but no difference in outcomes seen



Higher plasma levels within 0-3 hours, but no difference after 6 hours

Fig. 2 Plasma prednisolone levels (mean values \pm 1 SE) after the oral administration of 20 mg prednisolone (○ - - - ○) and 20 mg prednisone (●—●) in six patients suffering from acute viral hepatitis. The levels after prednisolone are significantly higher at one, two, and three hours ($t = 2.57, 2.95, \text{ and } 2.25; P < 0.05, < 0.05, \text{ and } < 0.05$ respectively).

Management of AH: Role of corticosteroids

- In 1978, Maddrey conducted RCT of 37 patients with biopsy-proven AH to receive prednisolone 40 mg daily for 28-32 days or placebo.
- Significant reduction in early mortality at 28 days in patients with severe AH were treated with corticosteroids (prednisolone 6% vs placebo 33%).
- Discriminant Function Analysis (DFA) demonstrated prothrombin time and serum bilirubin most accurately predicted survival.

○ Mean change from onset values adjusted by analysis of covariance.

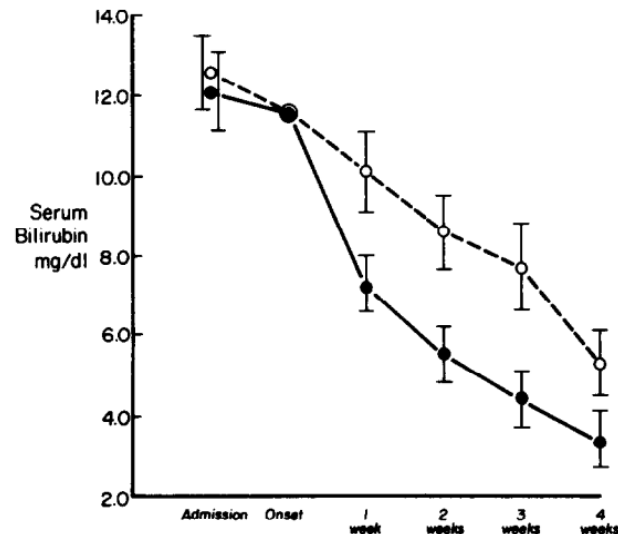
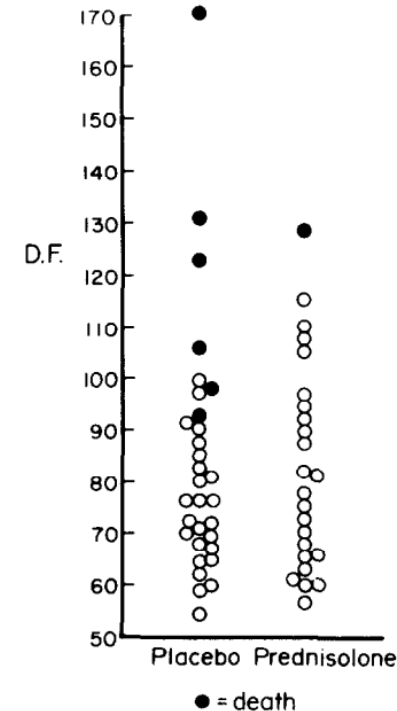


FIG. 1. Serum bilirubin at weekly intervals in prednisolone (solid line) and placebo (broken line) treated patients. In this and subsequent figures the values on admission and at weekly intervals after onset of therapy have been adjusted to a common onset mean (see text). Bars represent ± 1 SEM.



Management of AH: STOPAH Trial

- RCT 1103 adult SAH patients (DF > 32) who received 1) placebo, 2) prednisolone 3) pentoxifylline 4) both pred/ pentoxifylline.
 - Pentoxifylline (PTX)– Anti-TNF activity + fewer side effect than steroids
 - Improves blood flow and potentially enhance renal perfusion (HRS)- RCT of 101 patients who received PTX or placebo inpatient survival better in the PTX group (75.5%) than placebo (53.9%).

Treatment Group	Patients (n = 1103)	Percent
Pred/ pentoxi	274	13.5
Pred/ placebo	277	14.3
Pentoxi/ placebo	276	19.4
Double placebo	276	16.7

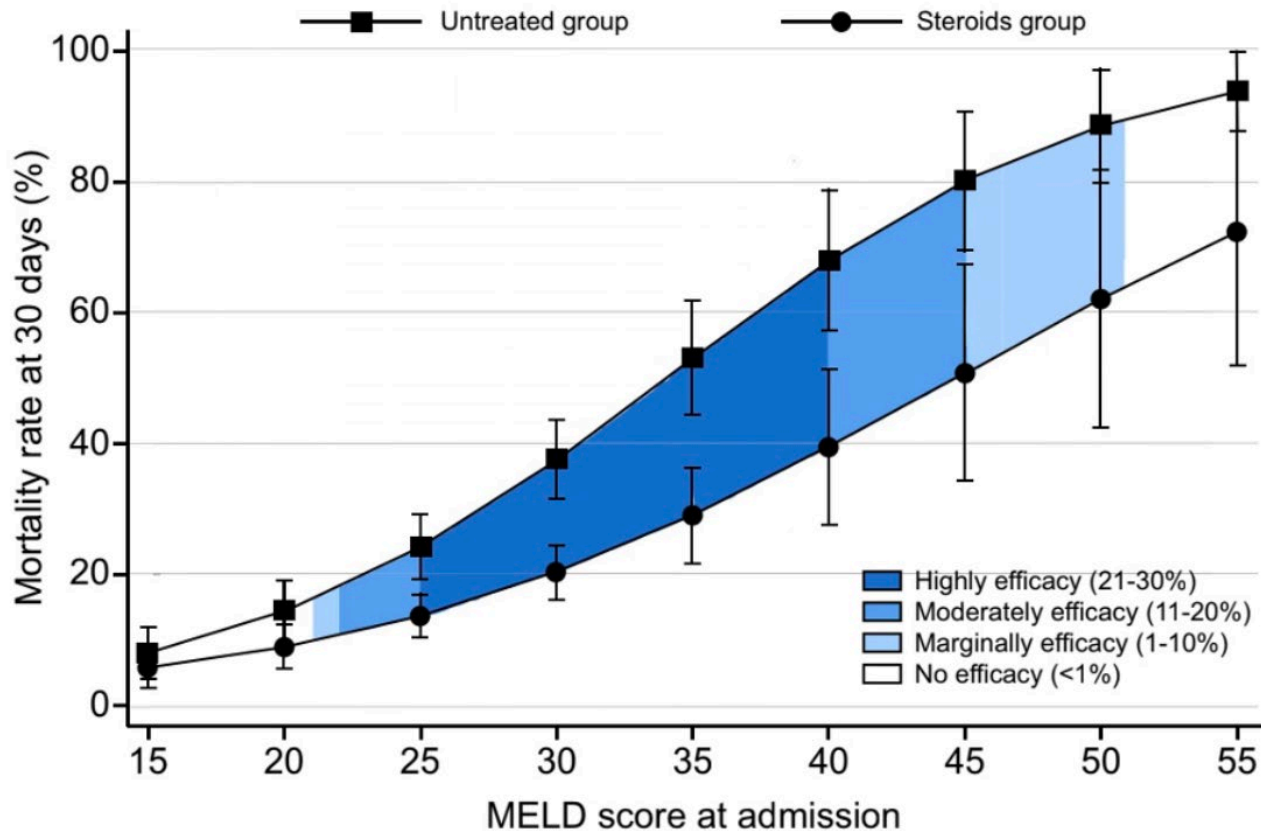
>28 days, neither drug was associated with a survival benefit

More infections in prednisone group compared to placebo (15% vs 8%)

Factor	Odds Ratio	P Value
Prednisolone	0.609	.015
PT ratio	1.380	.002
Bilirubin	1.002	.003
Age	1.050	<.001
WCC	1.030	.037
Urea	1.065	.037
Creatinine	1.564	.028
HE	3.073	<.001

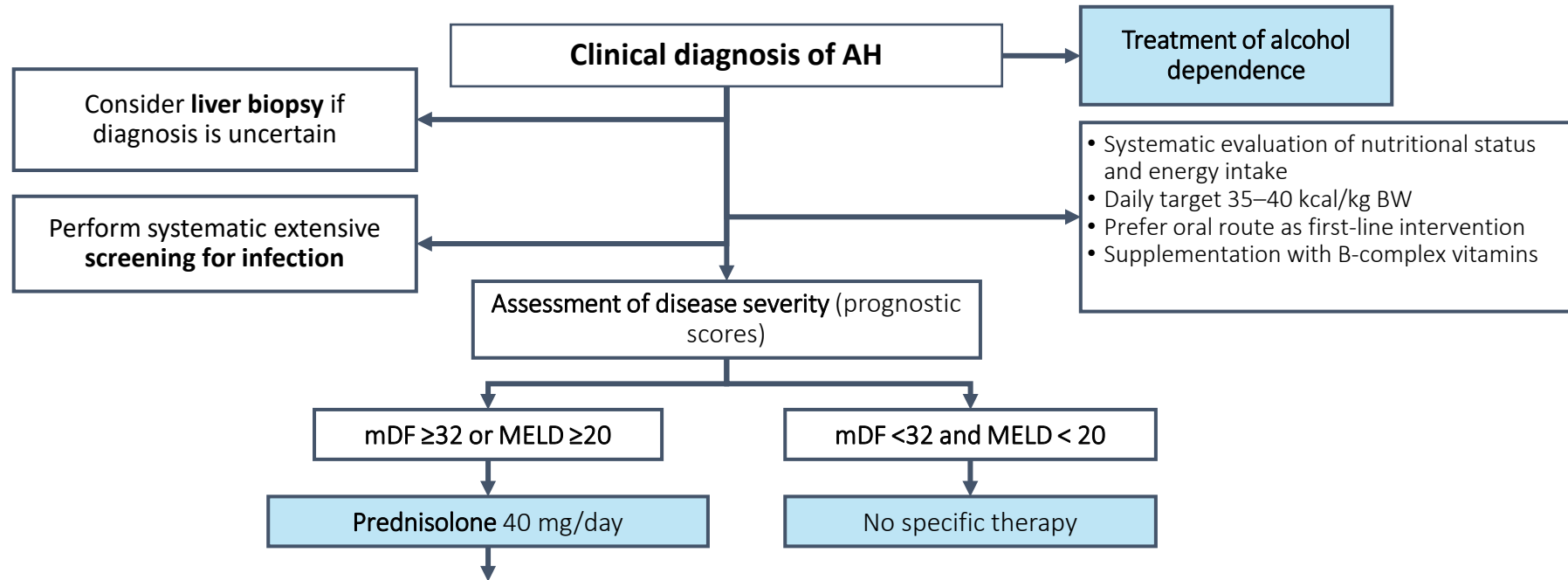
Management of AH: What is optimal therapeutic window?

3,380 adults with AH across 53 centers in 17 countries
43.5% received corticosteroid therapy



- Corticosteroids decreased mortality at 30 days (HR 0.59)
- Survival benefit seen only with SAH with MELD scores between 21-51
- Maximum benefit with MELD 25-39
- A MELD score >51 can be used for “futility” of corticosteroid treatment
- Survival benefit was not sustained at 90 or 180 days

Management of AH: Treatment algorithm



How long to determine treatment response?

Management of AH: Lille Score – Treatment Response

- 320 AH patients treated with corticosteroids for 28 days and baseline and change in bilirubin at day 7.
- Lille score ≥ 0.45 classified as corticosteroid non-responders.
- 40% had Lille score ≥ 0.45 and were non-responders and accounted for 45% of deaths.
- Lille score of ≥ 0.45 had a markedly decreased 6-month survival (25% versus 85% $P < 0.01$)

Lille Model-PT:

Compute

Reset all fields

Day 0 / / (dd/mm/yyyy)

Date of Birth / / (dd/mm/yyyy)

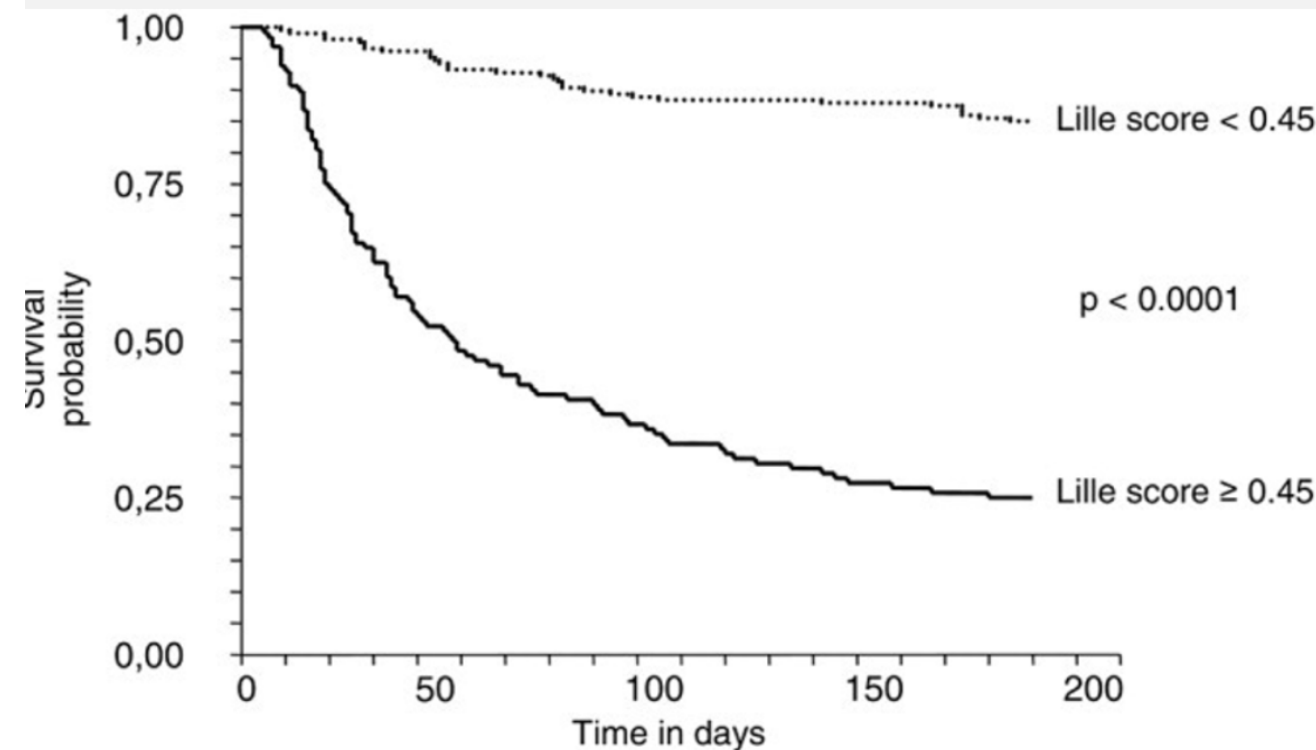
Bilirubin $\mu\text{mol/L}$ (at Day 0)

$\mu\text{mol/L}$ (at Day 7)

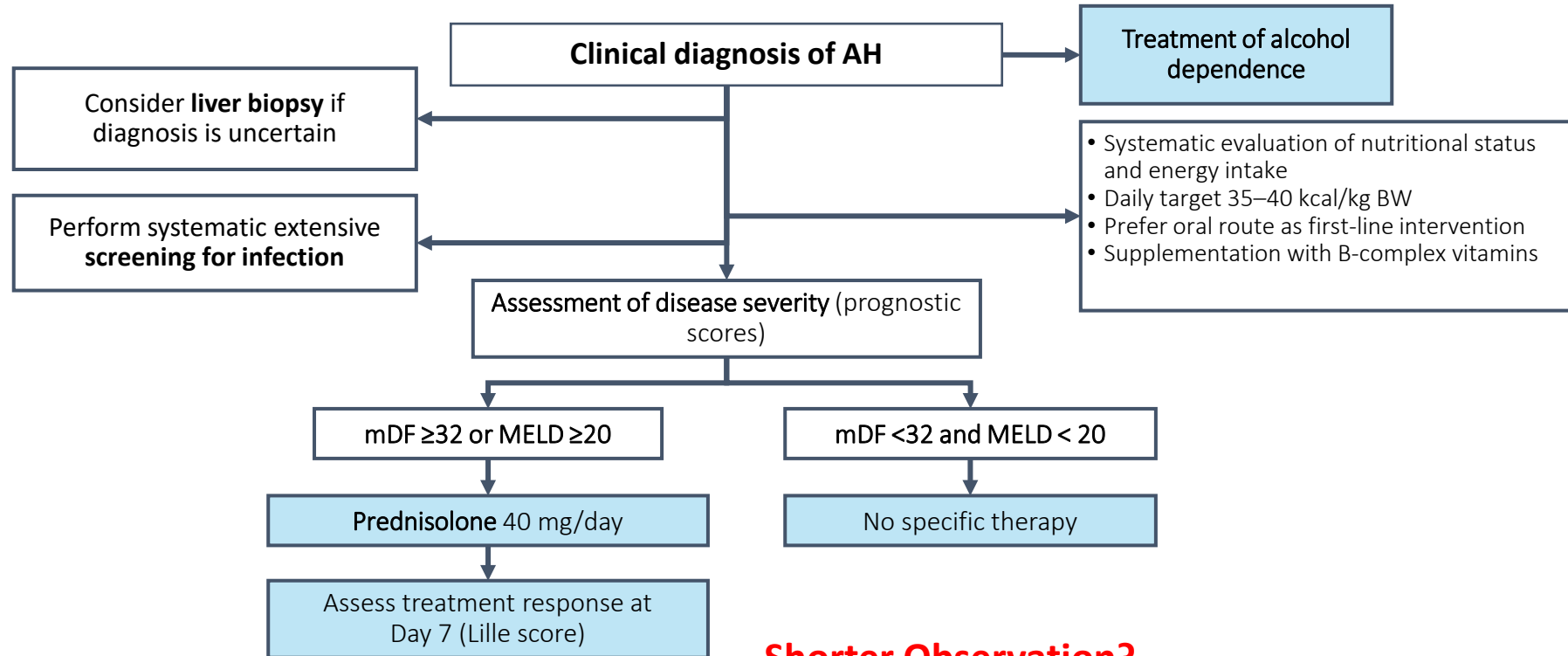
Creatinine $\mu\text{mol/L}$ (at Day 0)

Albumin* g/L (at Day 0)

Patient's prothrombin time sec (at Day 0)



Management of AH: Treatment algorithm

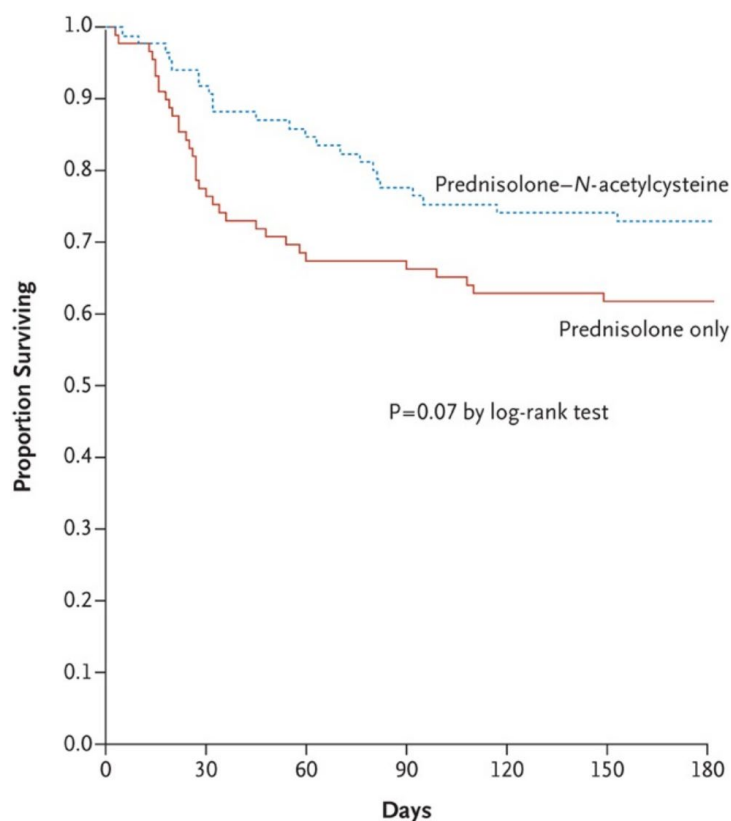


Shorter Observation?

Lille score at Day 4 vs Day 7: 91.1% agreement between LS4 and LS7 to predict response to therapy (p<0.001).

Management of AH: N-acetyl cysteine (NAC)

- Treatment with an **antioxidant (N-acetylcysteine)** and glucocorticoids could reduce inflammatory process and reconstitute cellular glutathione.
- 174 patients with SAH assigned to receive either prednisolone plus N-acetylcysteine or only prednisolone
- Both groups received 40 mg of oral prednisolone per day for 28 days
- For the first 5 days, patients in the prednisolone–N-acetylcysteine group received intravenous infusions of N-acetylcysteine

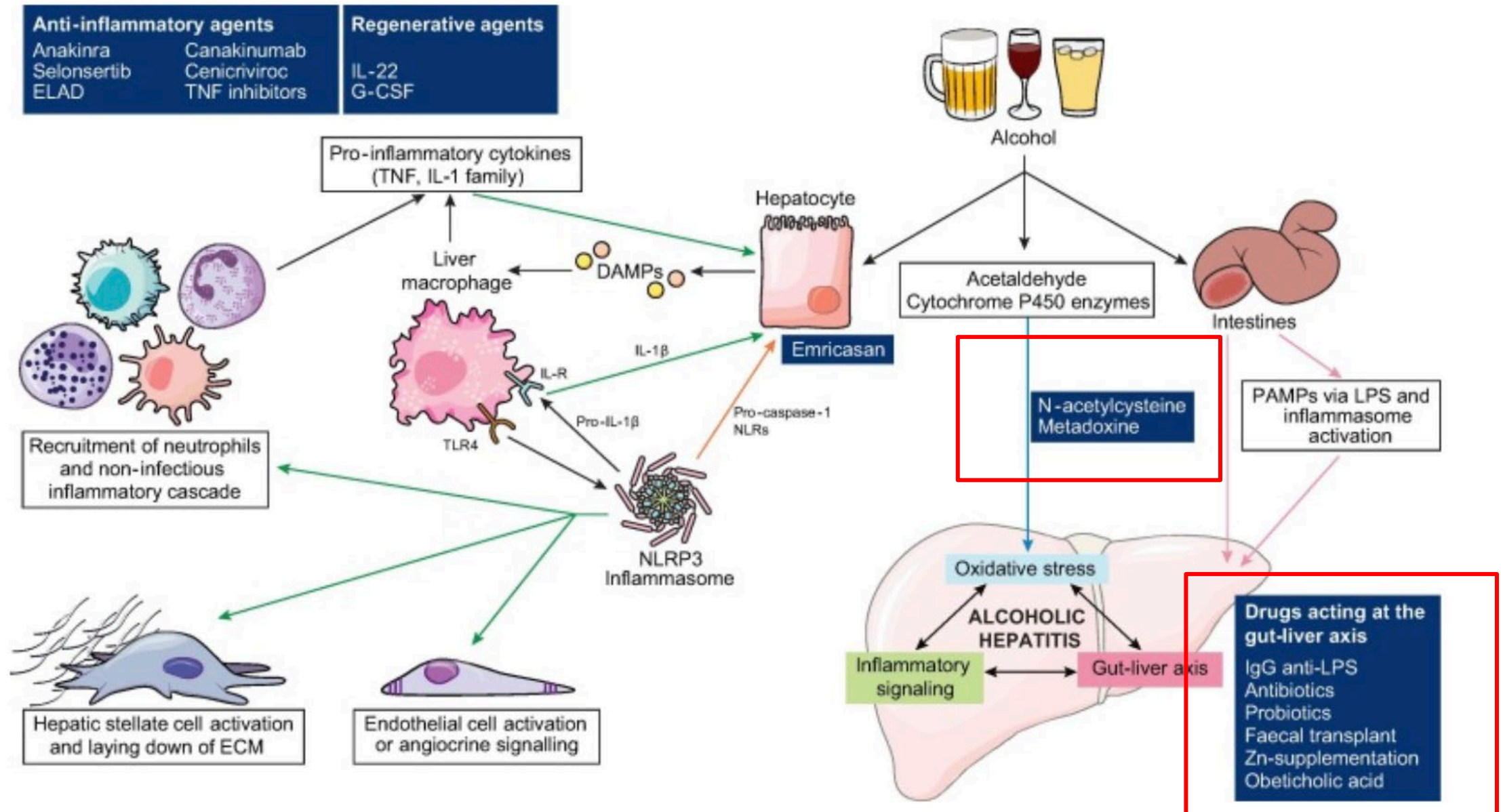


No. at Risk

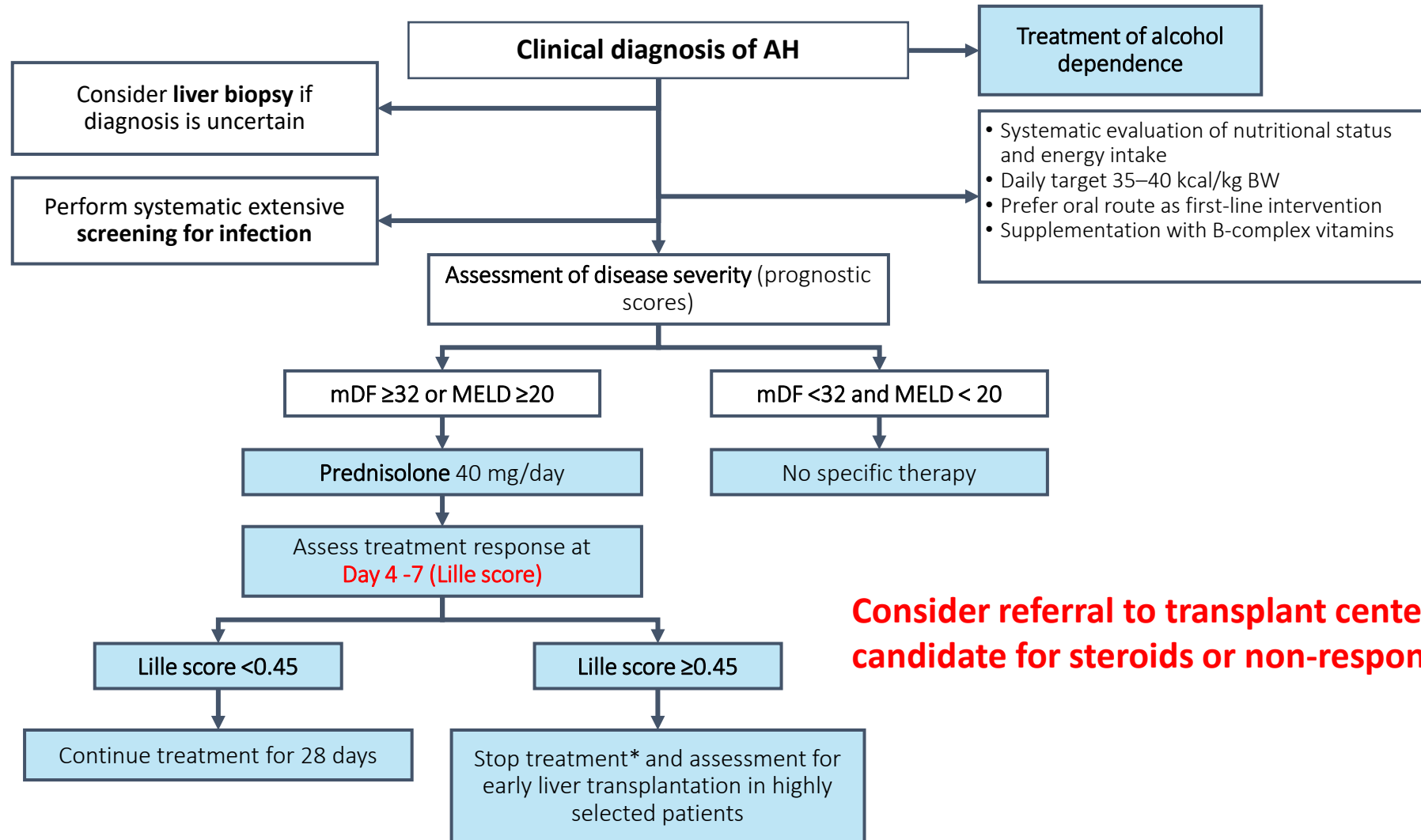
Prednisolone only	89	69	61	60	56	55	46
Prednisolone– N-acetylcysteine	85	78	73	66	63	63	48

- **Survival benefit at 1 month seen in prednisolone–N-acetylcysteine group compared to prednisolone only group (Mortality: pred 24% and pred-NAC 8% at 1 month (HR, 0.58; 95% CI, 0.14-0.76)**
- **Survival benefit with prednisolone–N-acetylcysteine or prednisolone groups not sustained at 6 months and 1 year**
- **At 6 months, 22% of the patients in the prednisolone-only group died of the hepatorenal syndrome, compared to 9% of the patients in the prednisolone–N-acetylcysteine group (OR 2.79; 95% CI, 1.08 to 7.42; P=0.02)**

Management of AH: Emerging Targets and Therapies

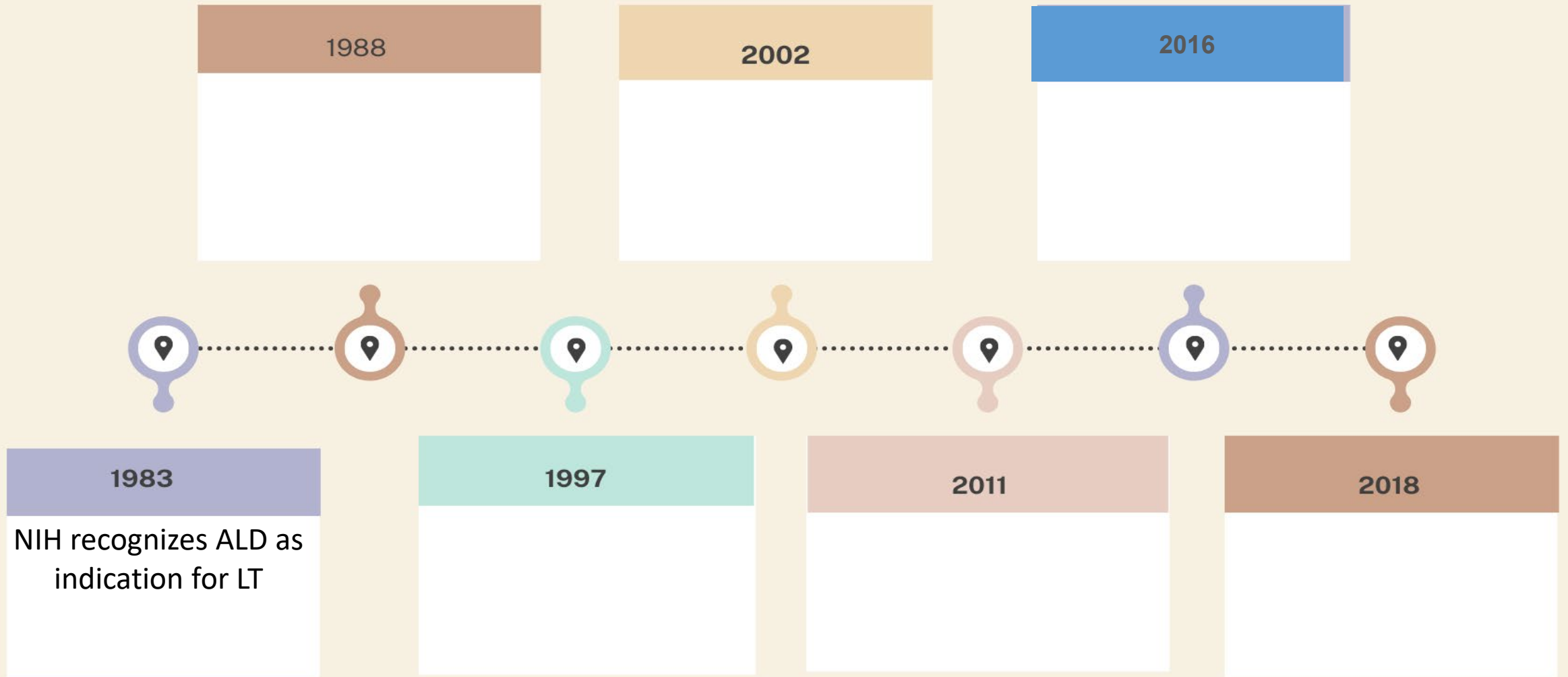


Management of AH: Treatment algorithm

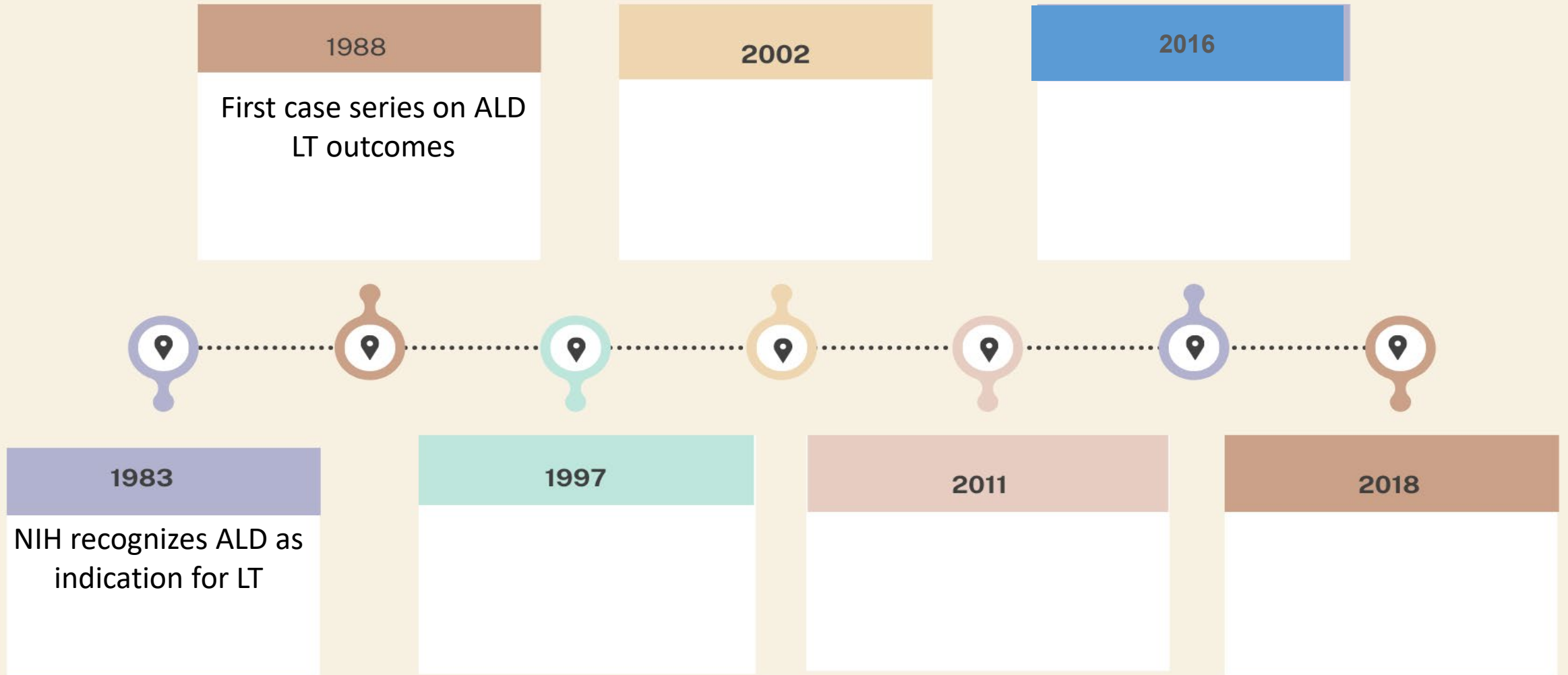


*Particularly in null responders (Lille score ≥ 0.56).
EASL CPG ALD. J Hepatol 2018;69:154–81

Liver transplantation for SAH: Role of liver transplantation



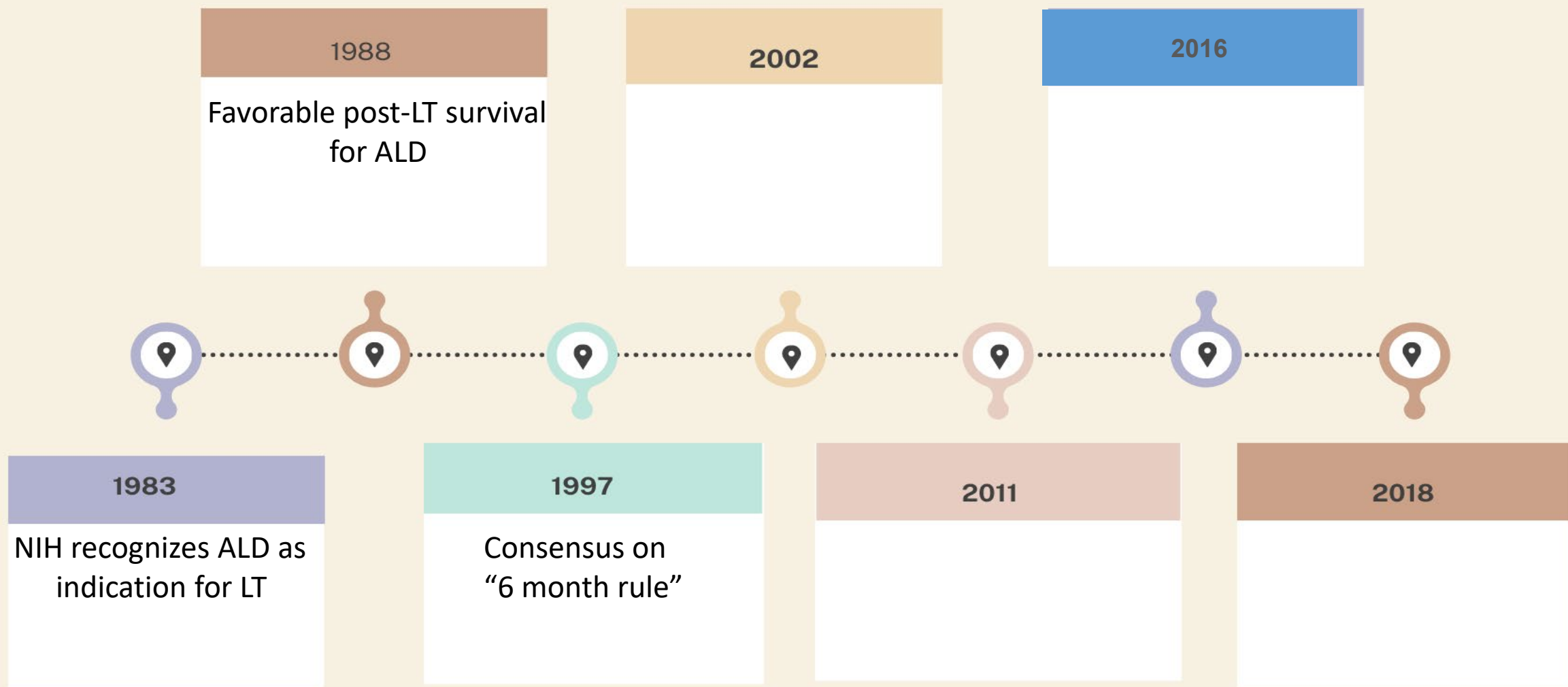
Liver transplantation for SAH: Role of liver transplantation



Liver transplantation for SAH: Role of liver transplantation

- 1983-1988 ALD constituted less than 10% of liver transplants.
- In 1988, Thomas Starzl reports case series of 41 patients with cirrhosis from ALD (1980-1987) with 1-year survival of 73%
 - Recidivism in only 2 recipients

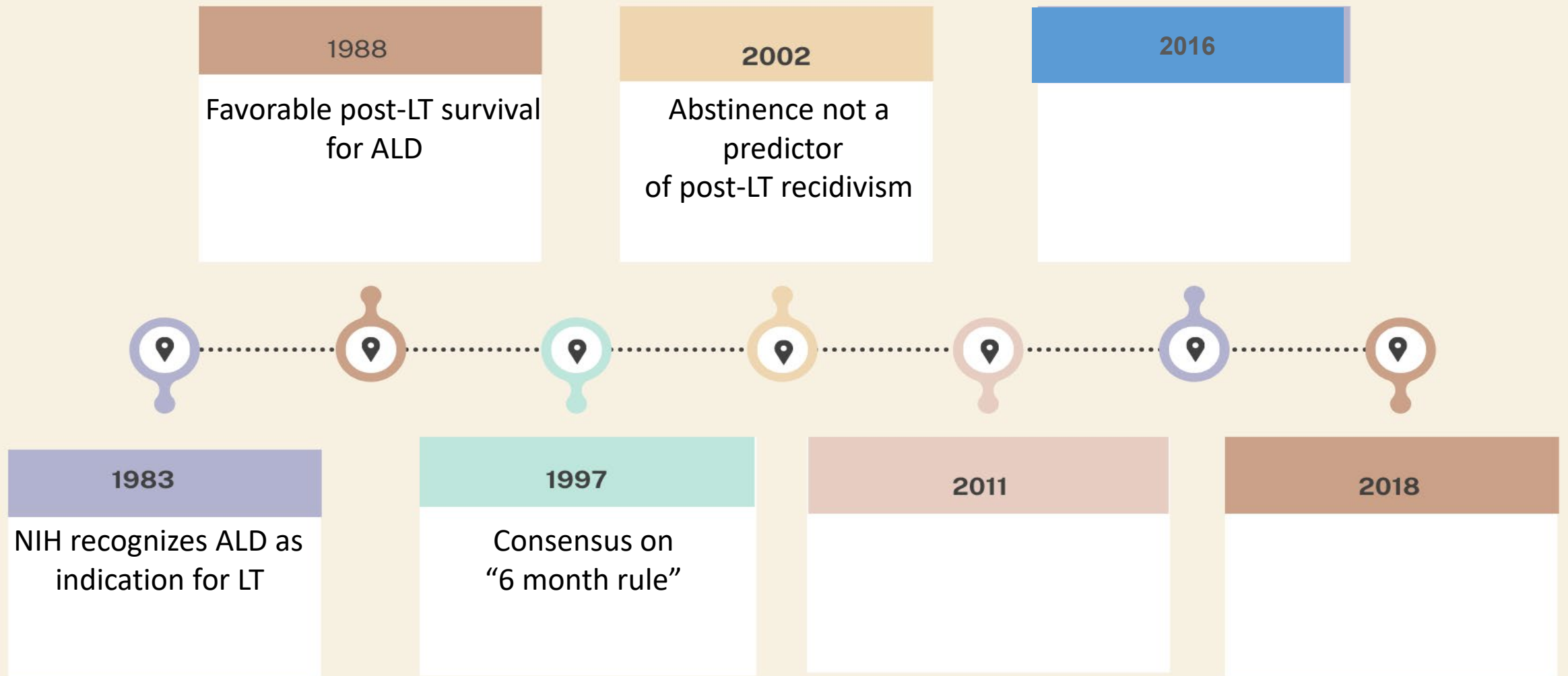
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Liver transplantation for SAH: Role of liver transplantation

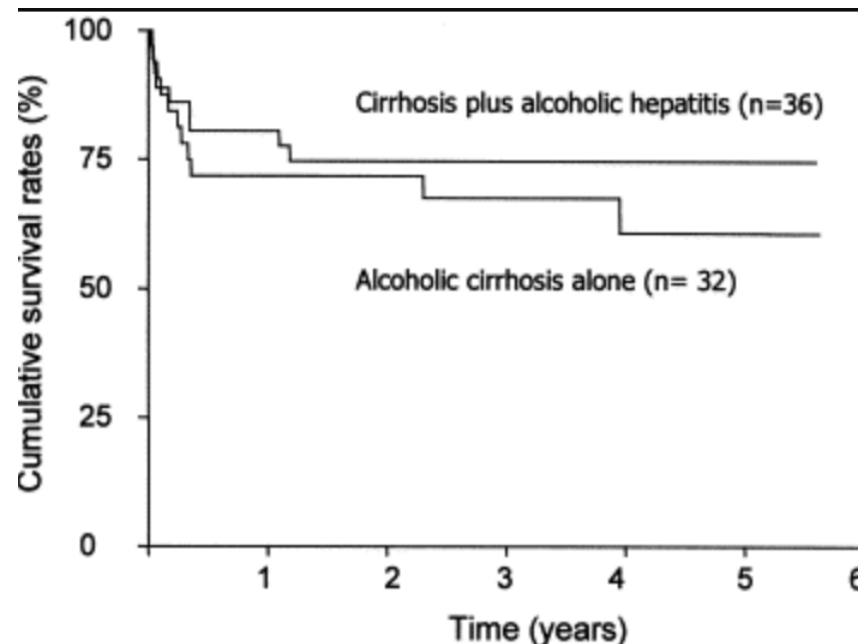
- 1997: AST consensus: 85% of LT programs reported requiring 6-month abstinence rule, thereby precluding SAH patients.
- The 6-month interval was justified on the grounds that it would allow patients to recover from the acute effects of alcohol-toxicity to the liver.
- In practice however, the so-called '6-month rule' became a surrogate for prediction of future drinking by ALD candidates for LT.

Liver transplantation for SAH: Role of liver transplantation

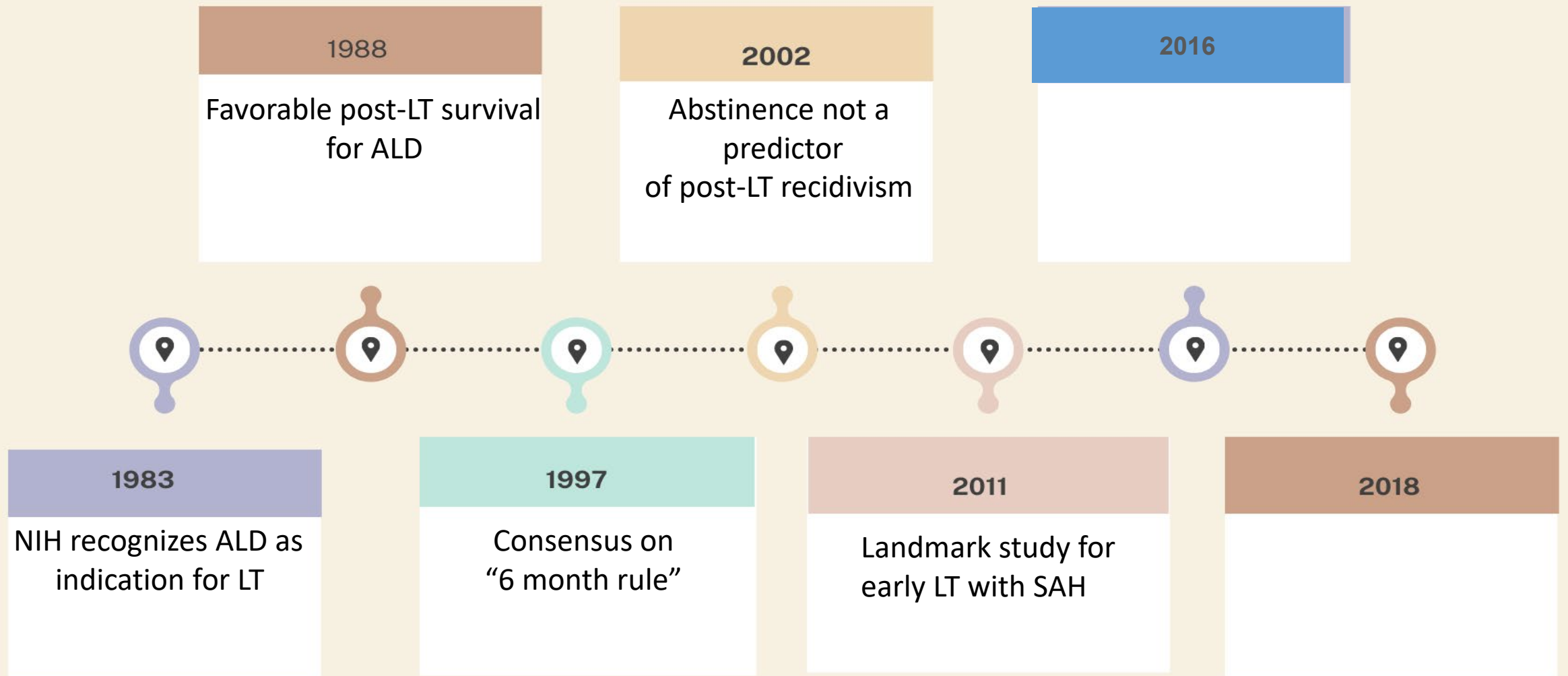


Liver transplantation for SAH: Role of liver transplantation

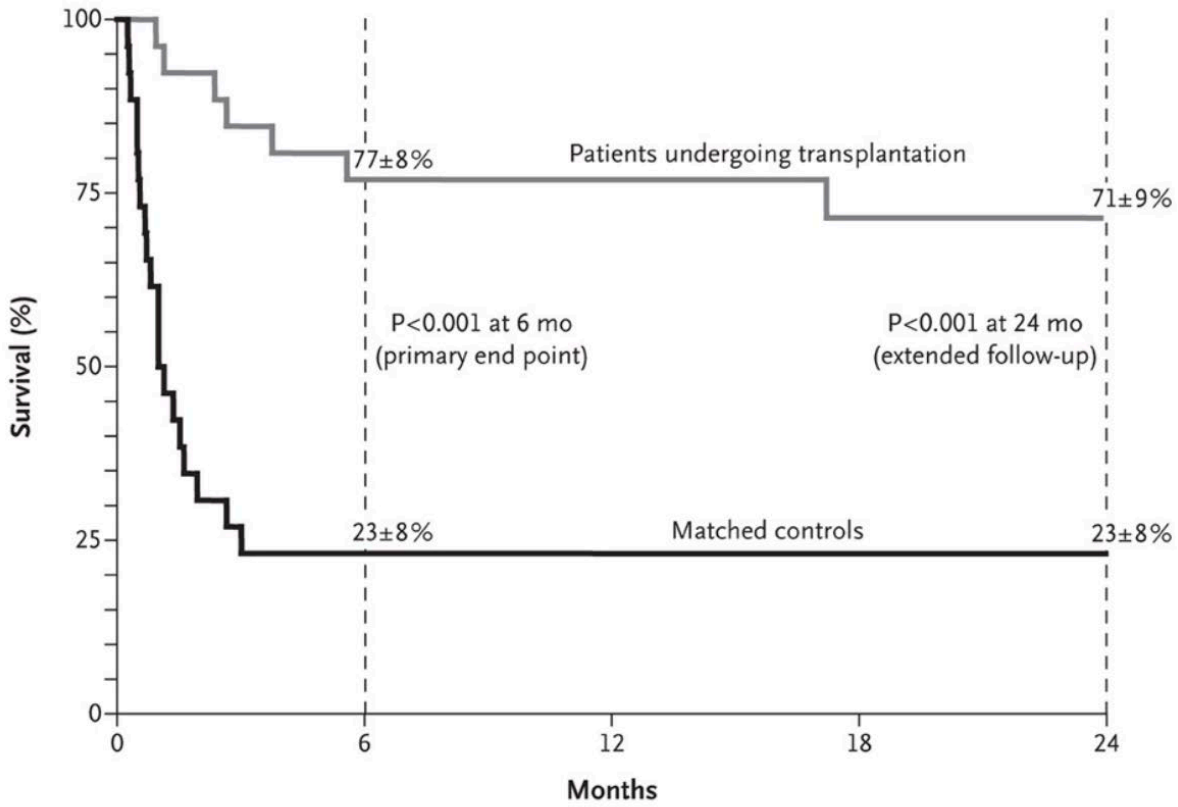
- In 2002, retrospective review of 68 explants with cirrhosis from ALD.
- 52% (n=36) had superimposed ASH suggesting SAH (hidden alcohol use)
- Overall recidivism rate was 10%. No difference between superimposed SAH compared to cirrhosis from ALD
- 1 year abstinence was predictive of post-LT abstinence, but not 6 months



Liver transplantation for SAH: Role of liver transplantation



Liver transplantation for SAH: Role of liver transplantation

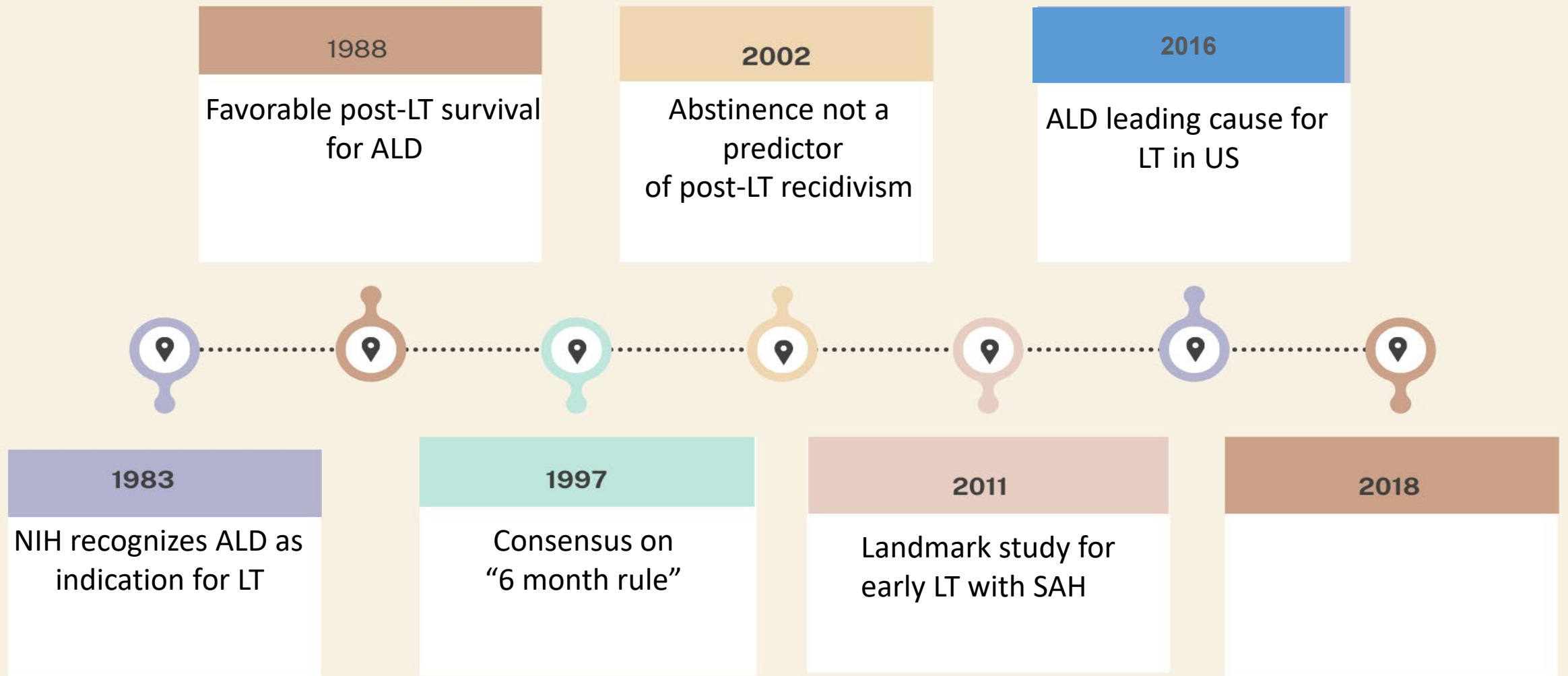


- 2011 – (2005-2010) 26 steroid patients with steroid-refractory SAH underwent LT.
- Median wait time 2 weeks.
- ITT survival (LT 77% vs no LT 23%).
- < 15% relapsed (n=3)

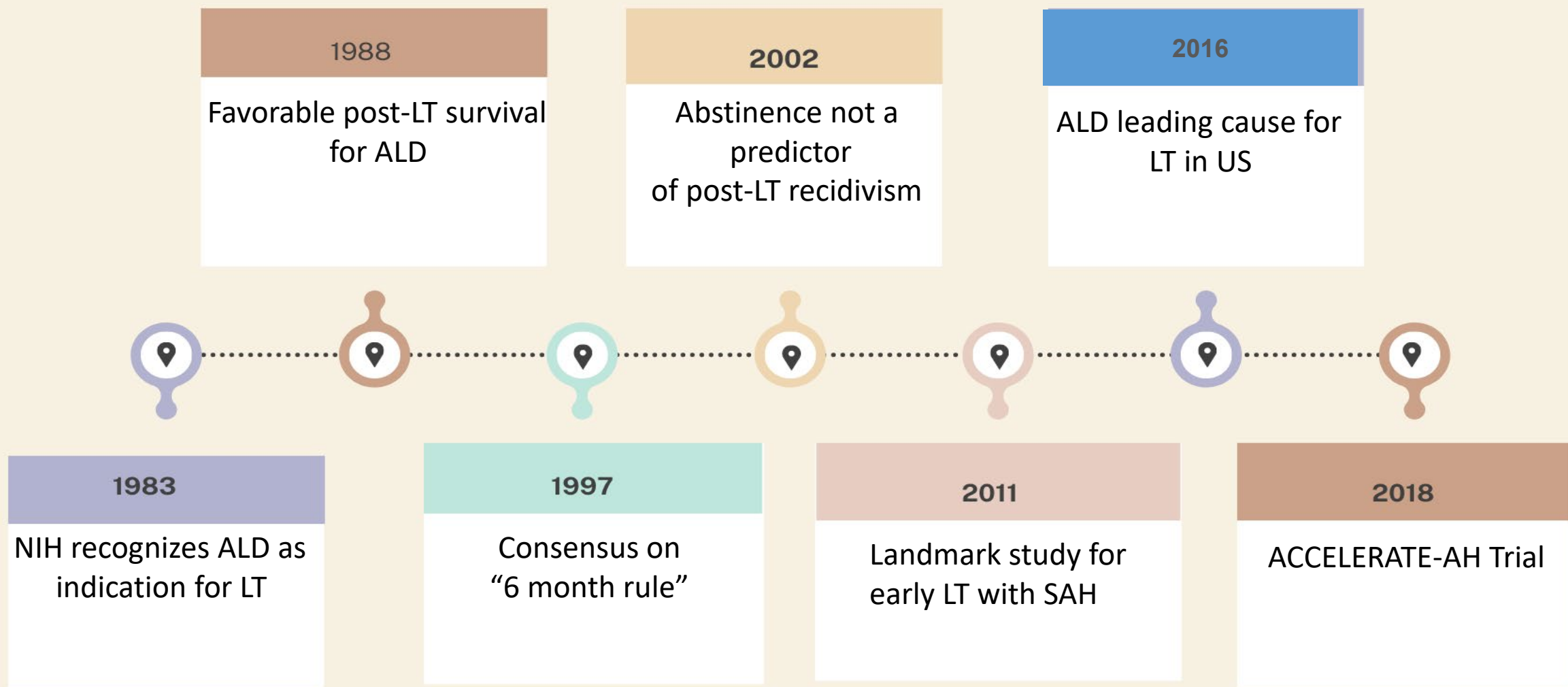
No. at Risk	0	6	12	18	24
Patients undergoing transplantation	26	20	15	14	13
Matched controls	26	6	6	5	4

Mathurin NEJM 2011.

Liver transplantation for SAH: Role of liver transplantation



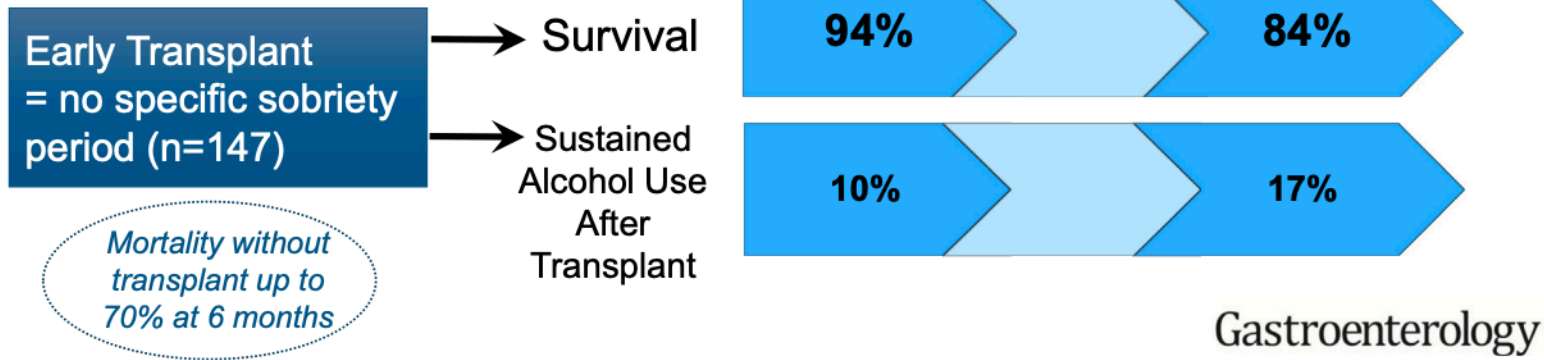
Liver transplantation for SAH: Role of liver transplantation



Liver transplantation for SAH: Role of liver transplantation

American Consortium of Early Liver Transplantation for Alcoholic Hepatitis: ACCELERATE-AH

12 centers in 8 UNOS regions



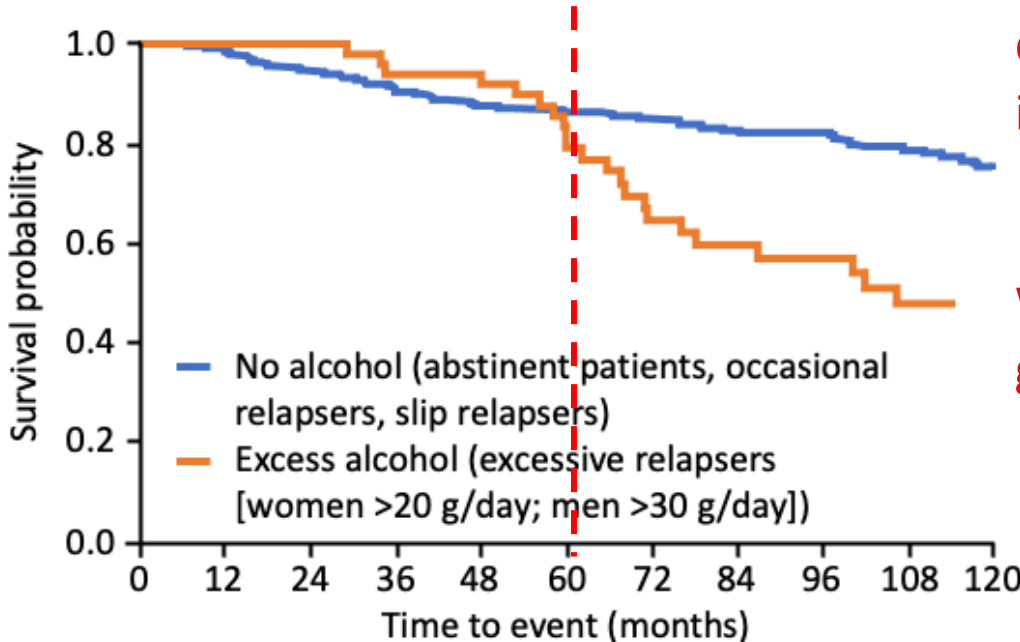
147 patients from 12 centers from 2006-2017

12 years – significant selection bias and generalizability

Lack of adherence to proposed psychosocial criteria for SAH listing between centers

Liver transplantation for SAH: Effect of recidivism on post transplant survival

Comparison of Kaplan–Meier survival curves between excessive alcohol relapsers and other patients



Graft and patient survival only negatively impacted after Year 5

Women and young adults at highest risk graft failure from recidivism.

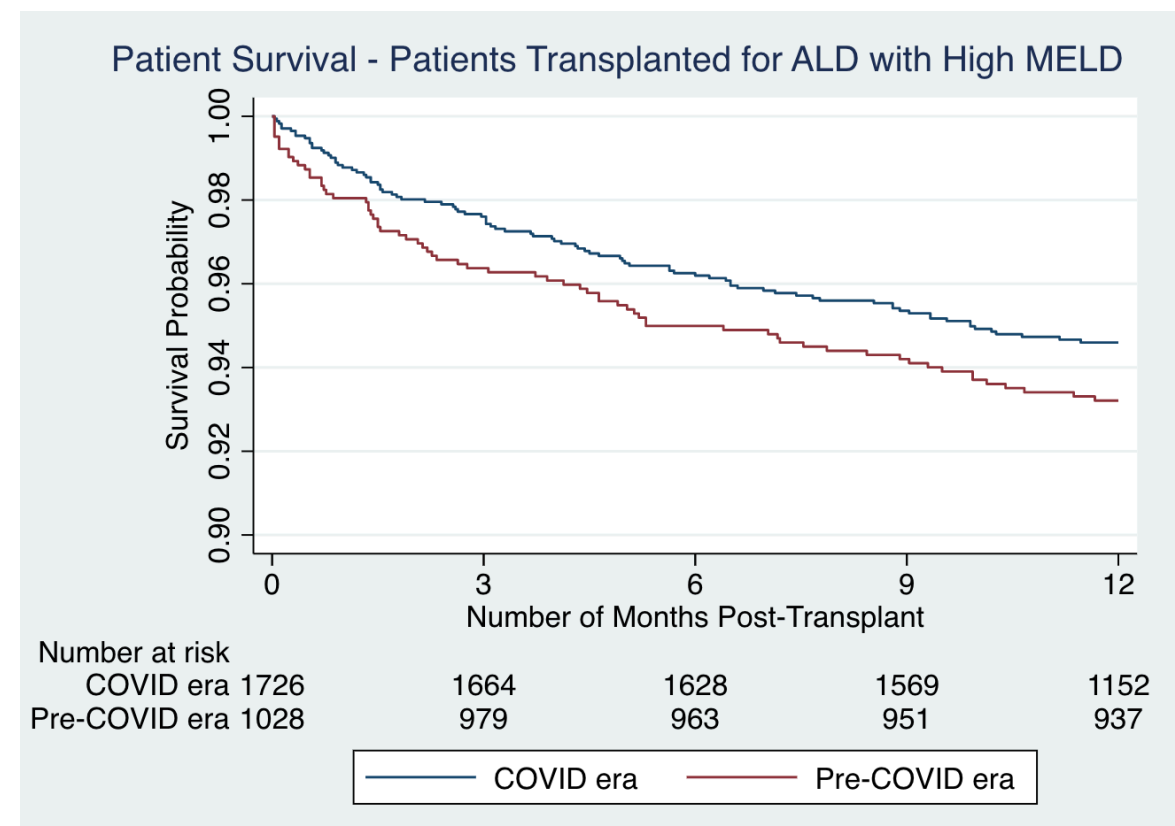
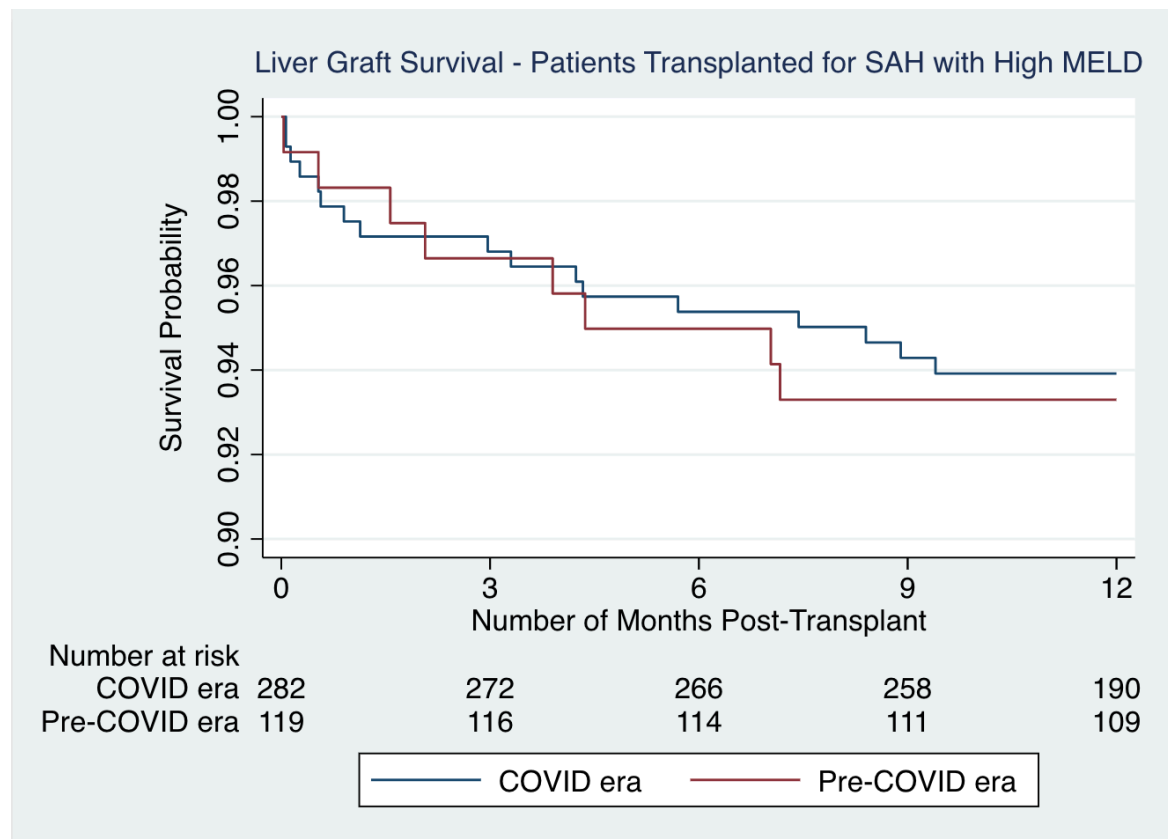
Patients at risk:

No alcohol	368	345	293	102
Excess alcohol	56	56	49	11

Faure S. J Hepatol 2012.
Pfitzmann R Liver Transpl 2007.

Liver transplantation for SAH: Evolve beyond one-year survival metric

One-year post-LT survival for SAH and ALD is excellent near 95%; leaves little room for improvement



Liver transplantation for SAH: Biomarkers of alcohol consumption

INDIRECT MARKERS

(GGT, ALT, AST, MCV)

Easy and inexpensive

Most frequently used markers
for early detection of ALD

Low sensitivity and specificity

No single marker or combination of markers
can differentiate between
different causes of liver disease

DIRECT MARKERS

(EtG, EtS, PEth)

Higher specificity (direct products
of ethanol metabolism)

Longer detection window vs. direct
determination of ethanol in blood or exhaled
air

Various confounding factors may
have an impact on results

Liver transplantation for SAH: Biomarkers of alcohol consumption

Biomarker	Sensitivity (%) Specificity (%)	Time to return to normal	Source	Comments
Direct biomarkers				
EtG ²⁷	62-91 88-98	2-5 d (12 h in serum but up to 7 d in urine)	Urine, serum, vitreous humor, hair, nails	UTI can result in false-negative results ²⁸
EtS ²⁷	70-95 78-93	2-5 d (12 h in serum but up to 7 d in urine)	Urine, serum, vitreous humor, hair, nails	Little clinical advantage over EtG alone, but if used in combination, sensitivity/specificity increase Not affected by UTI ²⁸
FAEEs ^{29,30}	> 75 > 75	24 h after last drink, or 99 h in heavy drinkers; up to several months in hair	Blood, hair	Can help distinguish between binge drinking and chronic alcohol use
PEth ³¹	94.5 ~100	21-28 d	Blood, dry blood spots	Most sensitive test and highly specific Reliable biomarker when liver-function test results cannot determine alcohol consumption in damaged liver

EtG, ethyl glucuronide; EtS, ethyl sulfate; FAEEs, fatty acid ethyl esters; MCV, mean corpuscular volume; PEth, phosphatidylethanol

Liver transplantation for SAH: Proposed Criteria for Evaluation

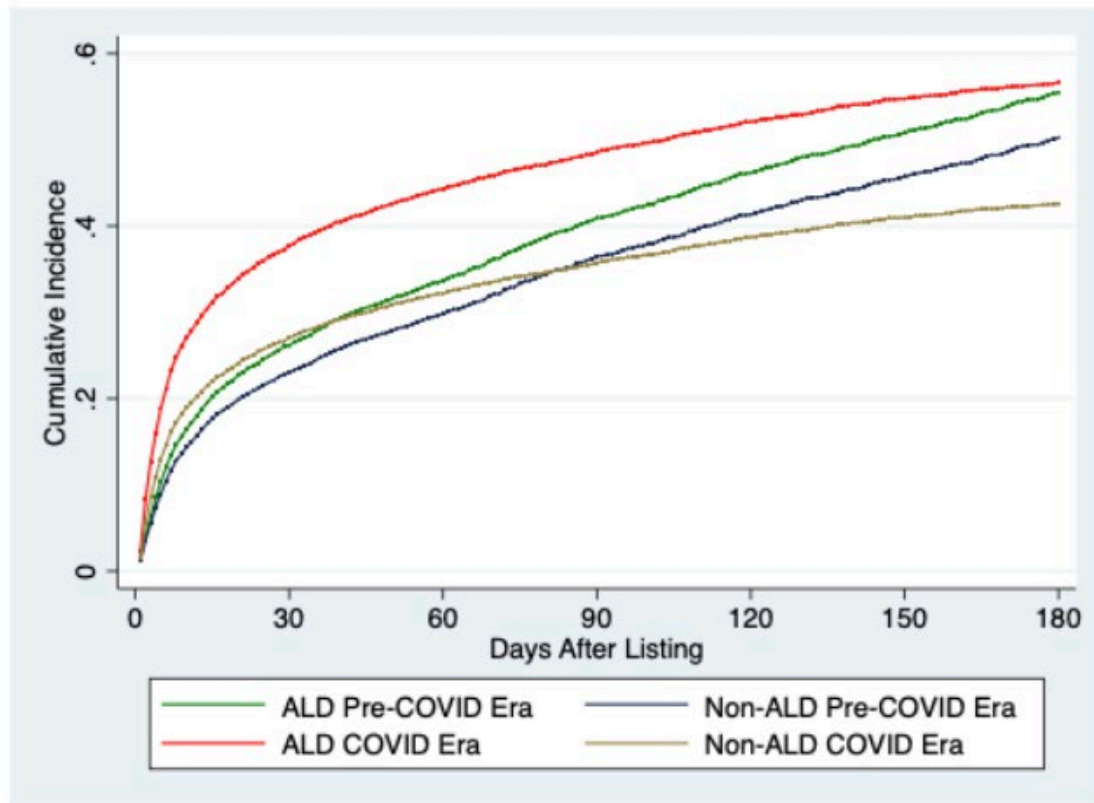
Table 2 Inclusion and exclusion variables for liver transplantation in alcoholic hepatitis	
Inclusion	Exclusion
Maddrey Discriminant Function >32 Model for End-stage Liver Disease (MELD) >20	Sepsis
Steroid non-responder (Lille ≥ 0.45) or ineligible for medical treatment	Severe comorbidities
Initial presentation of alcohol-related liver decompensation	Prior alcohol-related liver decompensating events
Favorable psychosocial profile	Poor psychosocial profile
Strong social support	Poor social support
Consensus of transplant selection committee	Severe psychiatric illness

Challenges for LT with AH: Psychosocial Assessment

Table 1 Scoring tools to predict alcohol relapse		
Tool	Factors Assessed	Relapse Prediction Score
Sustained Alcohol Use Post-Liver Transplantation (SALT) score ¹⁷	<ol style="list-style-type: none"> 1. Number of drinks 2. Failed rehabilitation attempts 3. AUD-related legal issues 4. Illicit drug use 	<p>SALT of ≥ 5 has 25% positive predictive value (PPV) (95% confidence interval [CI], 10%–47%) and 95% negative predictive value (NPV) (95% CI, 89%–98%) and specificity of 84% (95% CI, 76%–90%) for sustained alcohol use after LT</p> <p>Setting the cutoff at the maximum SALT score of 11 has a 50% PPV (95% CI, 1%–99%), 92% NPV (95% CI, 86%–96%), and specificity of 99% (95% CI, 95%–100%)</p>
Stanford Integrated Psychosocial Assessment for Transplantation (SIPAT) ¹⁸	<ol style="list-style-type: none"> 1. Patient willingness (5 items) 2. Social support (3 items) 3. Psychological stability (5 items) 4. Lifestyle and effect of substance use (5 items) 	Total SIPAT ≥ 21 with a Pearson's coefficient of 0.853, $P < .001$
Alcohol Relapse Risk Assessment (ARRA) ¹⁹	<ol style="list-style-type: none"> 1. Absence of hepatocellular carcinoma 2. Tobacco dependence 3. Alcohol use after liver disease diagnosis 4. Low motivation for alcohol treatment 5. Poor stress management skills 6. No rehabilitation relationship 7. Limited social support 8. Lack of nonmedical behavioral consequences 9. Engagement in activities with alcohol present 	<p>The ARRA score was predictive of relapse to any alcohol use after liver transplant (log rank $\chi^2 = 57.9$, $P < .001$) and relapse intensity for those who relapsed ($\chi^2 = 15.7$, $P = .003$)</p> <p>ARRA I (score 0, relapse rate 0%) ARRA II (score 1–3, relapse rate 8%) ARRA III (score 4–6, relapse rate 57%) ARRA IV (score 7–9, relapse rate 75%)</p> <p>Supporting the clinical utility of the ARRA score is an area under the curve of 0.892, indicating that the probability that a patient who relapsed to alcohol use would have a higher ARRA score is 89.2%</p>
High-Risk Alcoholism Relapse (HRAR) ²⁰	<ol style="list-style-type: none"> 1. Duration of heavy drinking 2. Usual number of daily drinks 3. Number of prior inpatient alcohol treatments 	<p>Low HRAR score 0–3 High HRAR score 4–6</p> <p>A high HRAR score was associated with a significantly higher risk of harmful alcohol use (odds ratio [OR], 10.7; 95% CI, 3.8–30.0) ($P < .005$)</p>

Challenges for LT with AH: Reducing access to LT for non-ALD

Cumulative incidence rates for liver transplantation among patients listed for ALD and non-ALD in the pre-COVID and COVID eras.

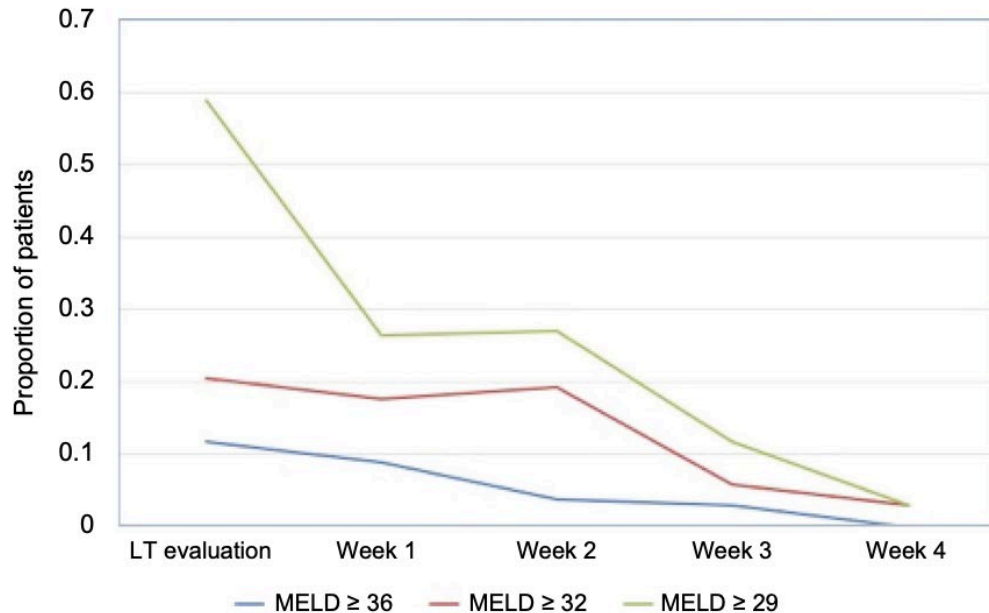


ALD candidates listed during COVID-19 pandemic had 50% higher rate of undergoing LT than non-ALD candidates (sHR 1.51, 95% CI: 1.42-1.60).

Challenges for LT with AH: “Recompensation” after wait listing

- Completed the evaluation and listing and patients MELD-Na has decreased from 40 to 20 over past week.

MELD trend in SAH patients who recovered (MELD < 20) after LT evaluation



Probability of recovery by age and peak MELD

	MELD < 35	MELD ≥ 35
Age < 45	0.81 (95% CI 0.54-0.96)	0.30 (95% CI 0.13-0.53)
Age ≥ 45	0.81 (95% CI 0.54-0.96)	0.03 (95% CI 0.00-0.18)

Unanswered question: How long should they remain on the wait list?

Patients who went on to recover did so quickly

Lower MELD, INR, and younger age are predictors for recovery

Summary

- MELD-Na greater > 20 to diagnose SAH and start steroid +/- N-acetylcysteine.
- Comprehensive infectious workup prior to starting corticosteroids.
- Response to corticosteroids and recovery can be assessed with Lille Score (Day 4 or 7).
- If no improvement with steroids within first 4-7 days, withdraw and refer to transplant center.
- Post-transplant survival for ALD and SAH are excellent; however long-term graft survival affected in those who relapse.
- PEth is an accurate and reliable biomarker for alcohol use in the pre- and post-transplant clinical care.
- No universal consensus on psychosocial assessment for evaluation and listing for SAH.

Thank you



Baylor
College of
Medicine

Thank You



Management of AH: Role of corticosteroids

- In 1971 RCT of 37 patients with biopsy-proven AH to receive prednisolone 40 mg daily or placebo.
- **Group I - severely ill with evidence of hepatic encephalopathy**, Group II moderately ill but no evidence of encephalopathy, and Group III mildly ill.

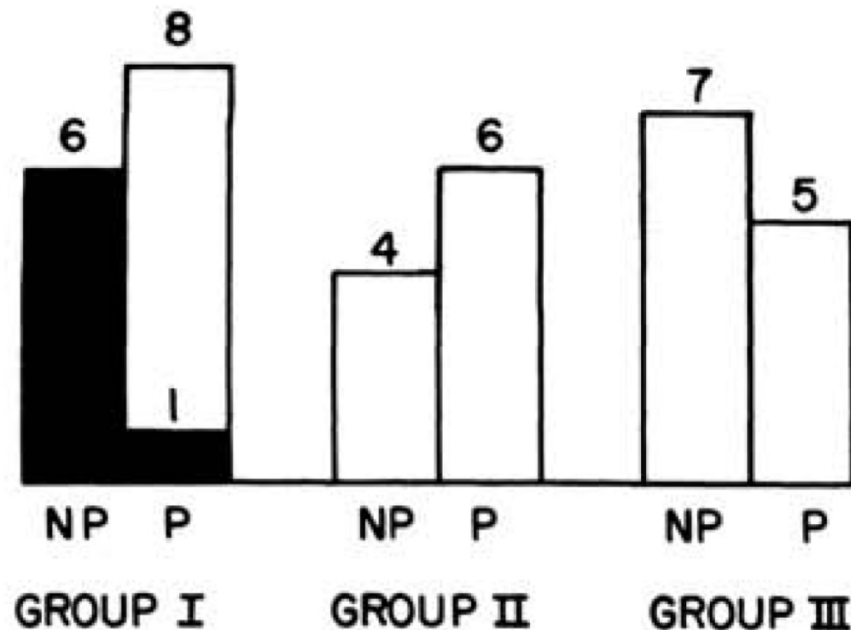


Figure 2. Mortality for each clinical severity group in 37 patients with alcoholic hepatitis. Numbers above bars refer to number of patients in category. Black areas indicate patients who died. All six group I patients given placebo died during the study; one of nine given prednisolone died in this group. P = prednisolone; NP = placebo.