HOSPITAL MEDICINE™ SUMMIT

Evidence-Based Care and Therapeutic Updates to Reduce the Risk for Rapid Progression and Recurrence of Hepatic Encephalopathy

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Learning Objectives

- Describe a plan of care for patients hospitalized with hepatic encephalopathy (HE) that is consistent with updated evidence-based recommendations
- Review the efficacy and safety of therapies for treatment of acute episodes of overt HE and prevention of their recurrence
- Identify crucial components of a transitional care plan to prevent future hospitalizations among patients with HE

Overview of HE

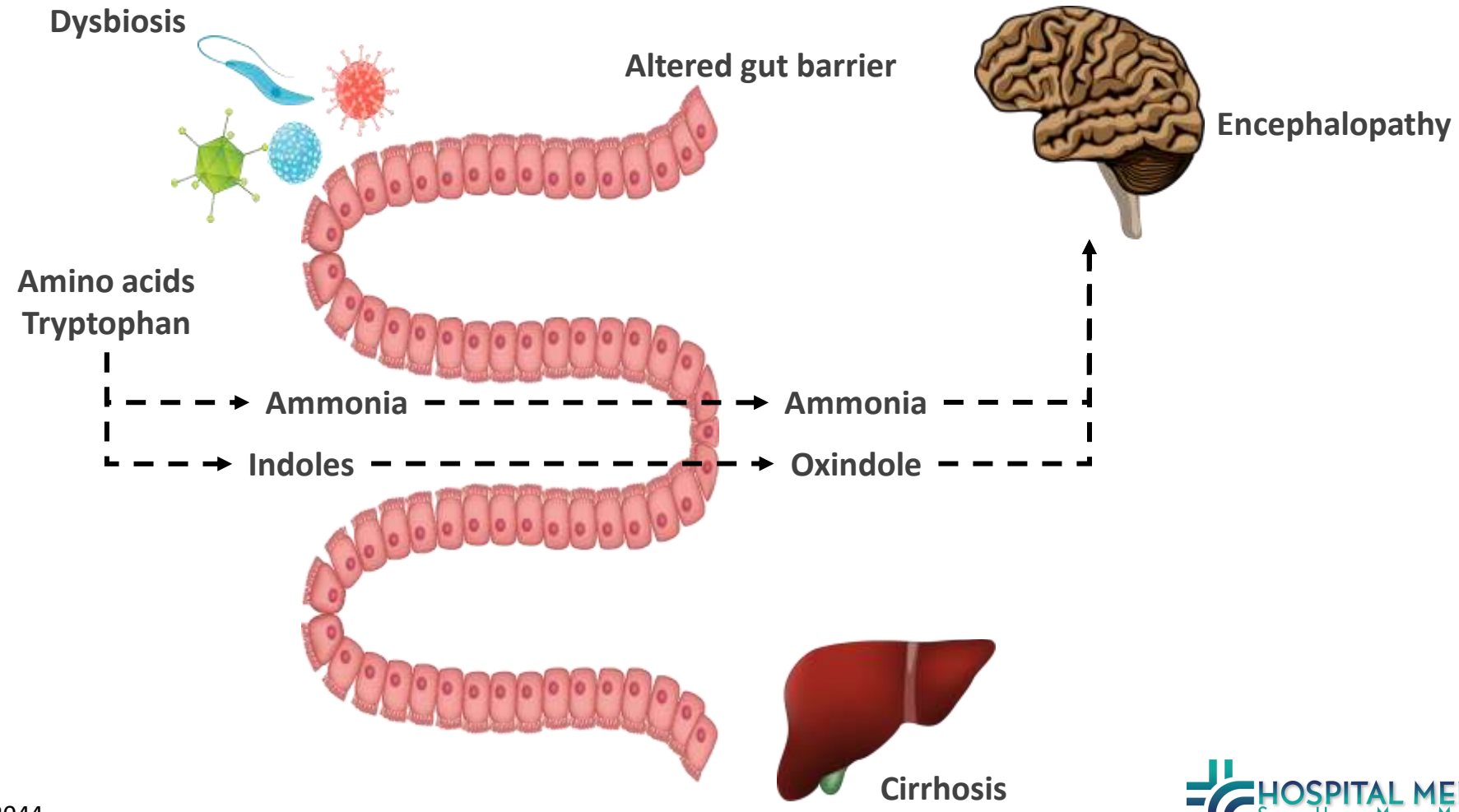
Hepatic Encephalopathy

- Important neuropsychiatric complication caused by liver insufficiency and/or PSS
- 30%–45% occurrence in patients with cirrhosis
- Affects an estimated 202,000 adults in the US (2018)
- Symptoms range from subclinical neurological or psychiatric alterations to coma
- High risk of recurrence, diminished HRQOL, and poor survival

HRQOL, health-related quality of life; PSS, portosystemic shunt.

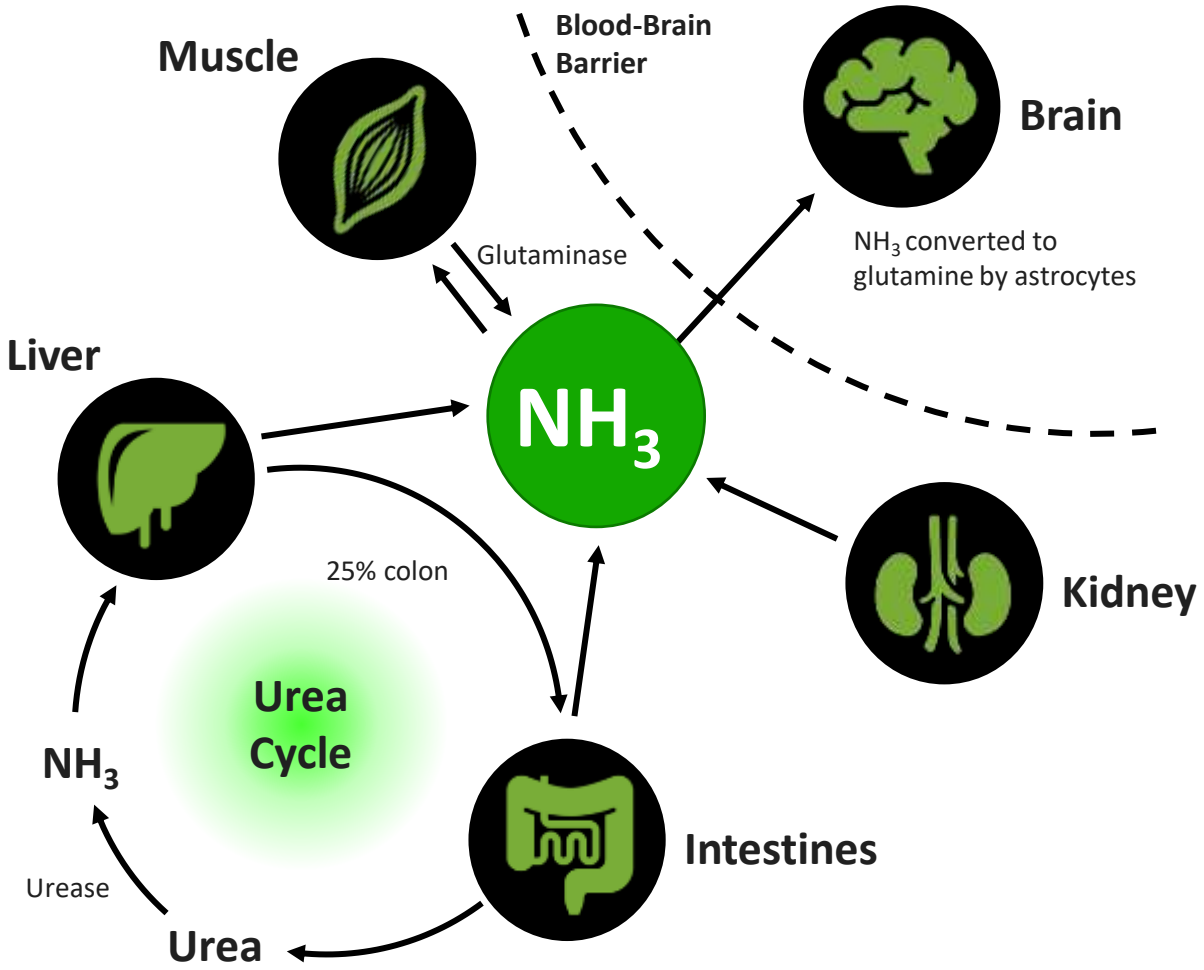
Chacko KR, et al. *Hosp Pract*. 2013;41(3):48-59; Poordad FF. *Aliment Pharmacol Ther*. 2007;25(suppl 1):3-9; Potnis A, et al. *Int J Hepatol*. 2021;2021:8542179. eCollection 2021; Vilstrup H, et al. *Hepatology*. 2014;60(2):715-735.

The Role of Gut Microbiota in Liver Disease and HE



Tilg H, et al. *Gut*. 2016;65(12):2035-2044.

Ammonia (NH_3) Underlies the Primary Pathophysiologic Mechanism of HE



- NH_3 is produced by bacterial metabolism of urea and proteins (gut) and deamination of glutamine (small intestine)
- Impaired hepatic metabolism of NH_3 and portal hypertension ➔ shunting of NH_3-rich portal blood to systemic circulation
- NH_3 crosses blood-brain barrier and is metabolized by astrocytes to glutamine
- Glutamine accumulation ➔ cerebral dysfunction

Elwis S, Rahimi RS. *J Clin Transl Hepatol*. 2017;5(2):142-151; Swaminathan M, et al. *Hepatic Med*. 2018;10:1-11.

Characteristics Associated With Poor Outcomes Following a Diagnosis of HE

Baseline Variable	Death		Hospital Days	
	Adjusted HR (95% CI)	*P* Value	Adjusted IRR (95% CI)	*P* Value
Age (per year)	1.02 (1.02, 1.03)	<.001	1.01 (1.01, 1.01)	<.001
Male	1.21 (1.19, 1.24)	<.001	1.03 (0.99, 1.06)	.116
End-stage renal disease	1.08 (1.01, 1.14)	.015	1.15 (1.06, 1.25)	<.001
Urban	1.01 (0.98, 1.04)	.707	1.04 (1.00, 1.09)	.063
Race (relative to White)				
Black	1.00 (0.96, 1.04)	.960	1.17 (1.10, 1.23)	<.001
Other	0.90 (0.87, 0.94)	<.001	0.97 (0.92, 1.03)	.353
Cirrhosis etiology				
Alcohol	0.82 (0.79, 0.85)	<.001	1.01 (0.94, 1.09)	.692
Hepatitis C	0.87 (0.85, 0.90)	<.001	1.20 (1.15, 1.25)	<.001
Hepatitis B	1.19 (0.88, 1.61)	.980	0.79 (0.75, 0.83)	<.001
Nonalcohol, nonviral cirrhosis	1.07 (1.02, 1.12)	.004	0.98 (0.93, 1.03)	.427

CI, confidence interval; HR, hazard ratio; IRR, incidence rate ratio.

Tapper EB, et al. *Aliment Pharmacol Ther*. 2020;51:1397-1405.

Characteristics Associated With Poor Outcomes Following a Diagnosis of HE (Continued)

Baseline Variable	Death		Hospital Days	
	Adjusted HR (95% CI)	*P* Value	Adjusted IRR (95% CI)	*P* Value
Time-varying covariates				
Gastroenterology consult	0.73 (0.67, 0.80)	<.001	1.07 (1.00, 1.14)	.056
Rifaximin	0.40 (0.39, 0.42)	<.001	0.35 (1.33, 0.37)	<.001
Ascites	4.20 (4.08, 4.32)	<.001	1.86 (1.79, 1.93)	<.001
Varices	1.03 (1.00, 1.06)	.029	0.77 (0.74, 0.80)	<.001
TIPS	1.15 (1.08, 1.23)	<.001	1.14 (1.05, 1.24)	.002
Hepatocellular carcinoma	2.27 (2.19, 2.34)	<.001	0.95 (0.91, 1.00)	.057
Charlson Comorbidity Index (CCI: relative to CCI 0)				
CCI=1	1.20 (1.17, 1.24)	<.001	1.17 (1.13, 1.22)	<.001
CCI=2	1.26 (1.22, 1.30)	<.001	1.28 (1.23, 1.34)	<.001
CCI ≥3	1.42 (1.35, 1.48)	<.001	1.33 (1.24, 1.42)	<.001

TIPS, transjugular intrahepatic portosystemic shunt.

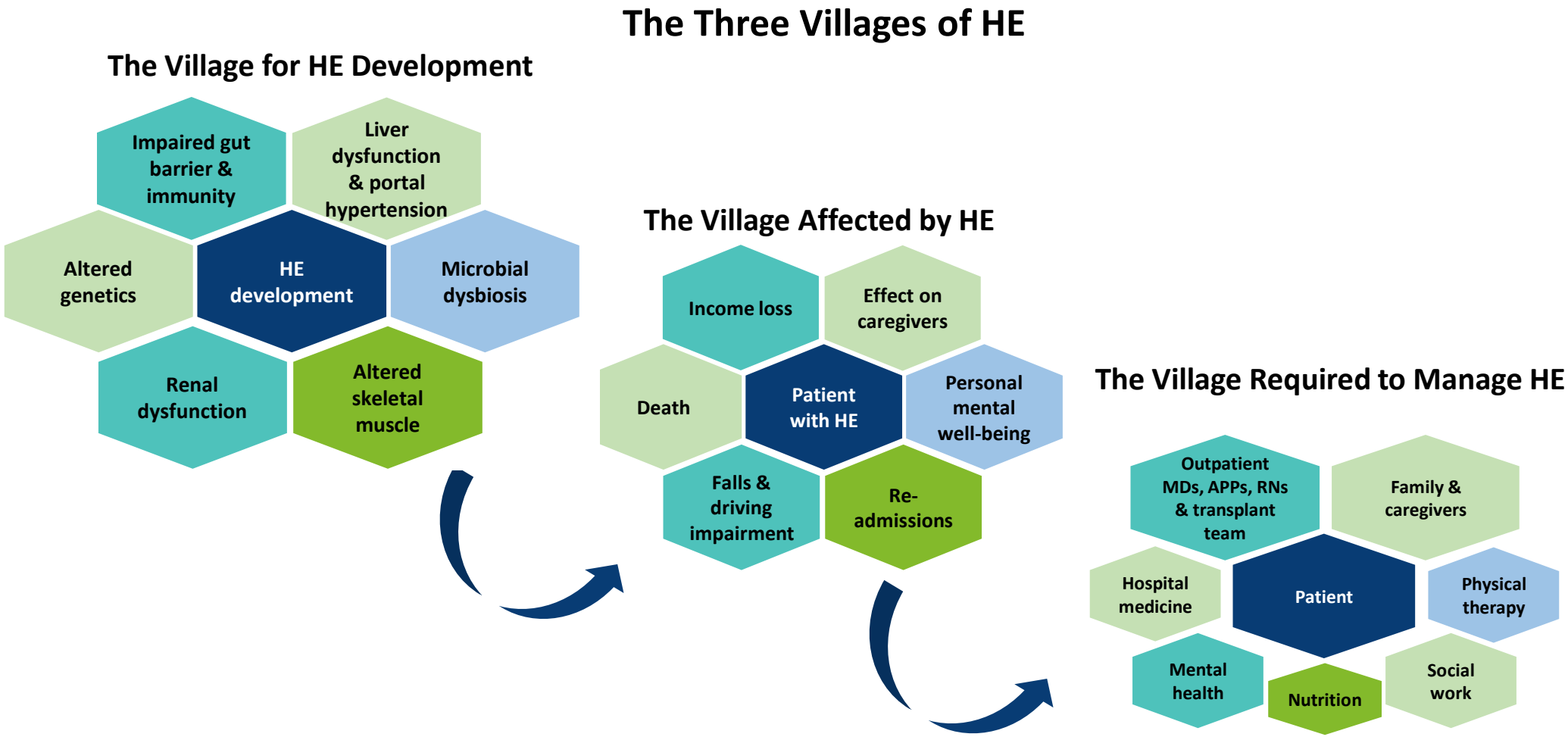
Tapper EB, et al. *Aliment Pharmacol Ther*. 2020;51:1397-1405.

CMS Announcement of First ICD-10 Code for Hepatic Encephalopathy

- Effective October 1, 2022, ICD-10 diagnosis code K76.82 took effect
  - Easy access to testing and treatment
  - Offers uniformity: Different codes for encompassing disease states caused issues with reimbursement and transitions of care
  - Improved documentation
  - Reduced misdiagnosis and mismanagement
  - Simplification of prior authorization process

Klein HE. New ICD-10 code aims to provide more insight into hepatic encephalopathy. Available at: https://www.ajmc.com/view/new-icd-10-code-aims-to-provide-more-insight-into-hepatic-encephalopathy

The Multilayered Impact of HE



Bajaj JS. *Am J Gastroenterol*. 2021;116:1184-1186.

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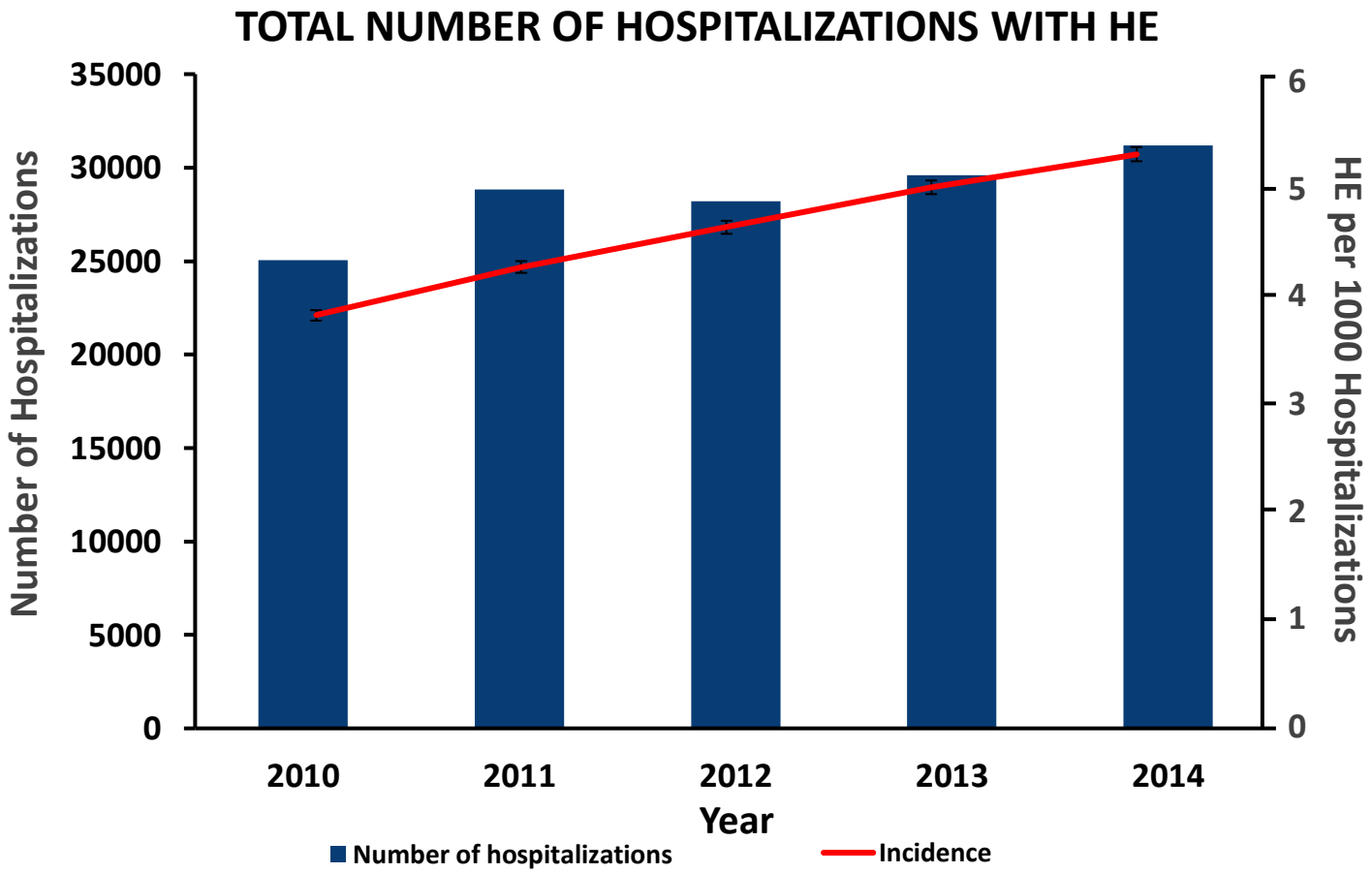
HE in the Hospital Setting

Trends in Hospitalizations With HE in the US



Hospitalized patients with cirrhosis and HE (2010–2014):

- Total hospitalizations ↑ **24.4%** (*graph*)
- Prolonged hospitalizations* ↑ **38%**
- In-hospital mortality ↑ **45%**

*Prolonged hospital stay was defined by a length of stay in the 75th percentile or higher.

Al-Taee AM, et al. *Eur J Gastroenterol Hepatol*. 2019;31(9):1165-1166; Hirode G, et al. *Dig Dis Sci*. 2019;64(6):1448-1457.

Factors Associated With Greater Risk for HE Among Hospitalized Patients With Cirrhosis

Portal hypertension

AHR: 3.42 with vs without

Cause of cirrhosis

AHR: 1.44 for alcohol-related vs NAFLD-related

Medication use

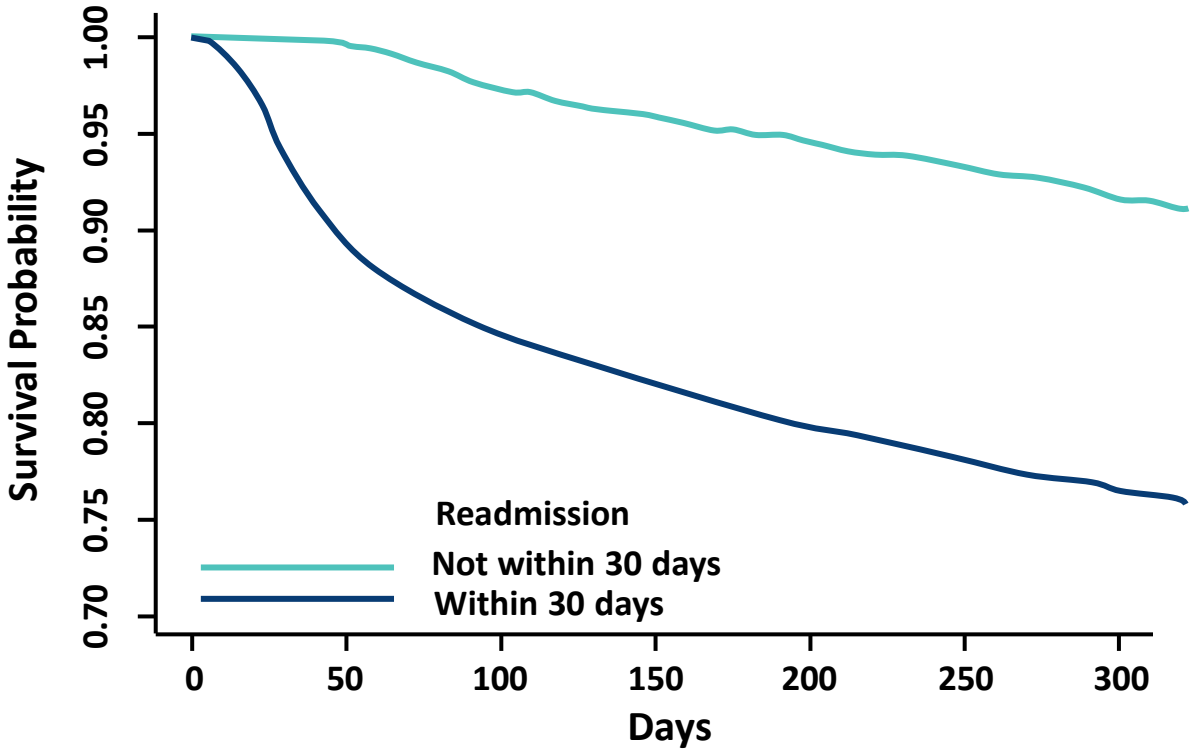
Benzodiazepines – AHR: 1.19
GABAergics – AHR: 1.17
Opioids – AHR: 1.24
PPIs – AHR: 1.41

AHR, adjusted hazard ratio; GABA, gamma-aminobutyric acid; NAFLD, nonalcoholic fatty liver disease; PPIs, proton pump inhibitors.

Tapper EB, et al. *Hepatol Commun*. 2019;3(11):1510-1519.

30-Day Readmission Is Associated With Poor Survival in Hospitalized Patients With HE

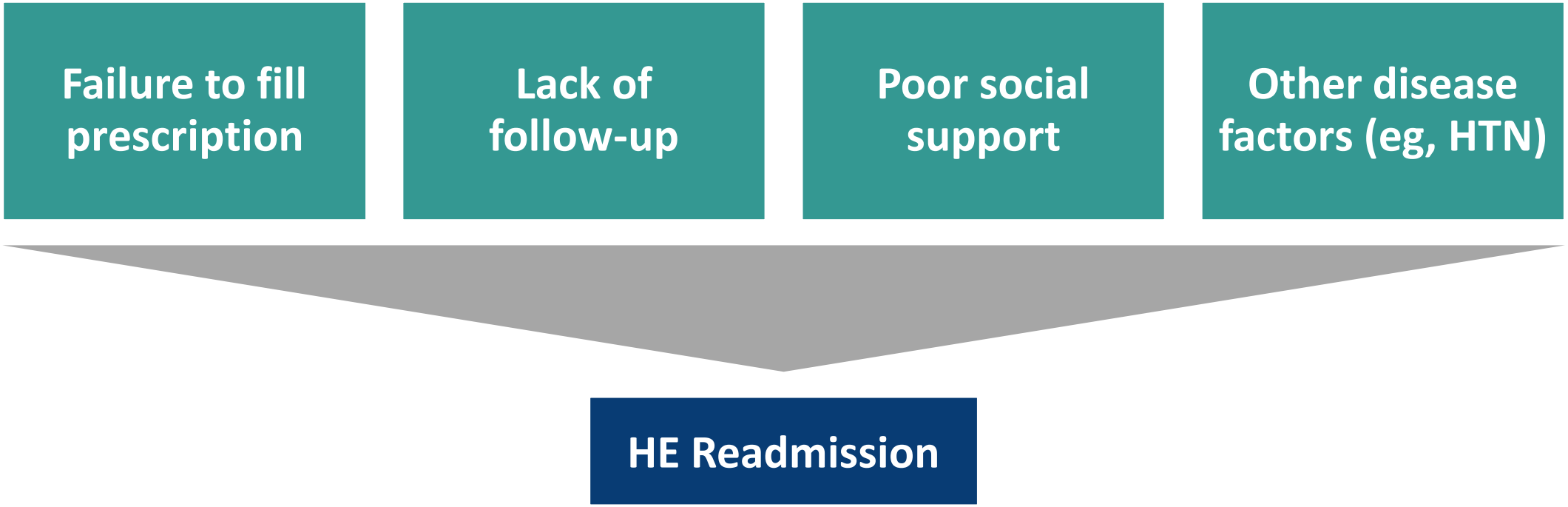
Probability of Survival With vs Without Readmission Within 30 Days Among Patients With HE



Patients readmitted ≤30 days of index hospitalization had significantly lower calendar-year survival vs those not readmitted ≤30 days (HR, 4.03; 95% CI, 3.50-4.66).

Kruger AJ, et al. *Ann Hepatol*. 2019;18(2):310-317.

Factors Contributing to HE Readmission



HTN, hypertension.

Neff G. *Hepatology*. 2013;58(S1):390A-391A; Rassameehiran S, et al. *South Med J*. 2016;109(6):365-369.

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Recognition and Diagnosis of HE

HE Types Based Upon Underlying Disease

Type	Underlying Disease
A	Acute liver failure
B	PSS or bypass
C	Cirrhosis

Vilstrup H, et al. *Hepatology.* 2014;60(2):715-735.

West Haven Criteria Minimal and Grade I HE

WHC	Description	Operative Criteria
Unimpaired	▪ No encephalopathy, HE history	▪ Normal test results
Minimal	▪ Alterations in psychomotor speed/executive functions or on neurophysiological measures ▪ No clinical evidence of mental change	▪ Abnormal results on psychometric or neurophysiological tests ▪ No clinical manifestations
Grade I	▪ Trivial lack of awareness ▪ Euphoria or anxiety ▪ Shortened attention span ▪ Impairment of addition or subtraction ▪ Altered sleep rhythm	▪ Orientation in time and space ▪ Cognitive/behavioral decay with respect to standard on clinical examination, or to caregivers

All conditions are required to be related to liver insufficiency and/or PSS.
WHC, West Haven Criteria.

Vilstrup H, et al. *Hepatology*. 2014;60(2):715-735.

West Haven Criteria Grades II, III, and IV HE

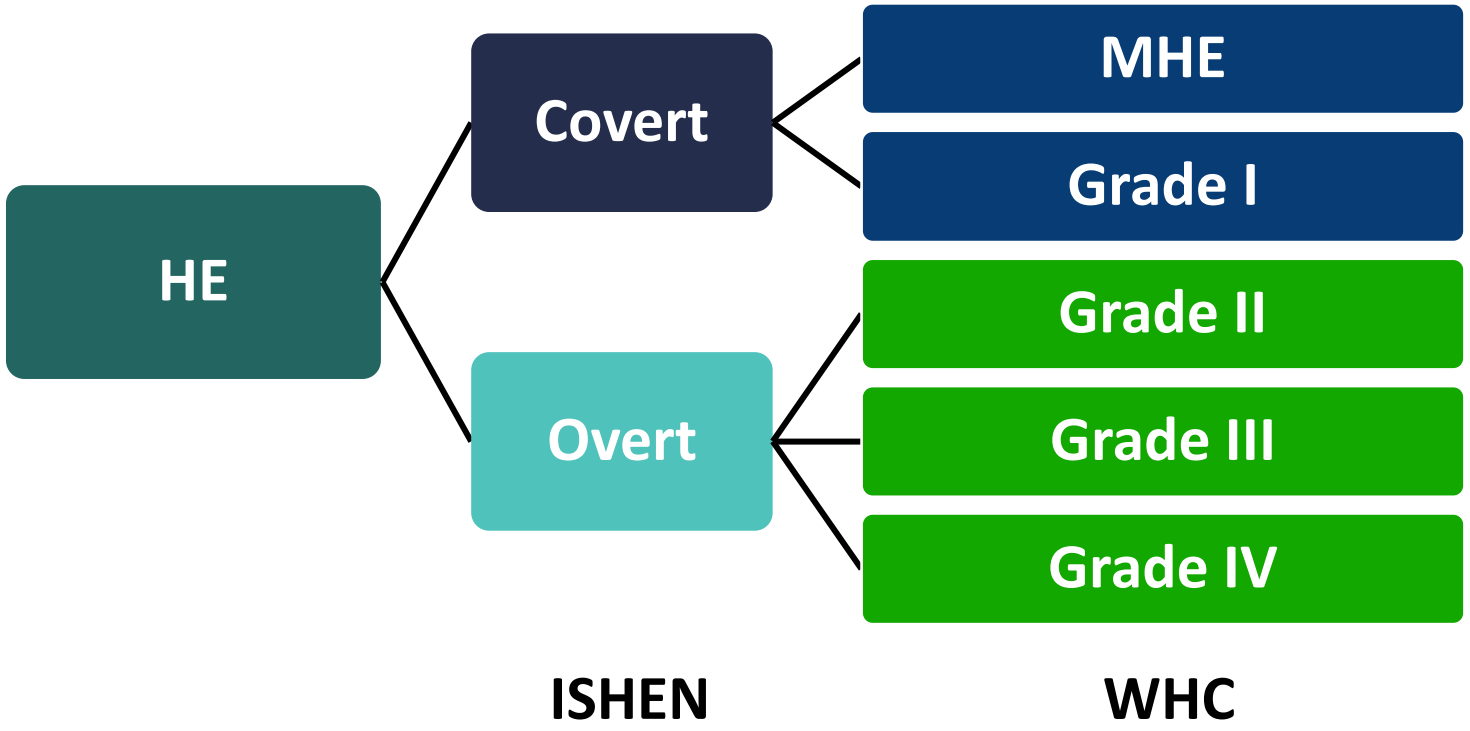
WHC	Description		Operative Criteria
Grade II	▪ Lethargy or apathy ▪ Disorientation for time ▪ Obvious personality change	▪ Inappropriate behavior ▪ Dyspraxia ▪ Asterixis	▪ Disoriented for time (≥3 of the following errors: day of month or week, month, season, or year) ▪ ± Other symptoms
Grade III	▪ Somnolence to semi stupor ▪ Responsive to stimuli ▪ Confused	▪ Gross disorientation ▪ Bizarre behavior	▪ Disoriented for space (≥3 of the following errors: country, state [or region], city, or place) ▪ ± Other symptoms
Grade IV	▪ Coma		▪ Does not respond even to painful stimuli

All conditions are required to be related to liver insufficiency and/or PSS.

Vilstrup H, et al. *Hepatology*. 2014;60(2):715-735.

Covert vs Overt HE

Poor reliability of *Grade I* staging has led to the classification of covert vs overt HE:



MHE, minimal HE.

Vilstrup H, et al. *Hepatology*. 2014;60(2):715-735.

Diagnosis and Staging of HE

Clinical Examination

Reliable markers
- Disorientation
- Asterixis

Easily overlooked markers
- Mild hypokinesia
- Psychomotor slowing
- Attention deficits

Staging Disease Severity

West Haven Criteria (gold standard)

Quantitative Testing

Only in study settings

Vilstrup H, et al. *Hepatology*. 2014;60(2):715-735.

Precipitating Factors for Overt HE

Precipitating Factor	%	Precipitating Factor	%
Dehydration	76	TIPS	13
Acute renal failure	76	GI bleeding	13
Lactulose nonadherence	53	Hyponatremia	13
Infections	42	Large-volume paracentesis	9
Constipation	40	High protein diet	0
Opioids and benzodiazepines	27	Unknown	0
Hypokalemia	20		

GI, gastrointestinal.

Pantham G, et al. *Dig Dis Sci*. 2017;62:2166-2173.

Diagnostic Tests

- Complete blood count
- Comprehensive metabolic panel
- Blood cultures
- Urine analysis and culture
- Chest x-ray
- Paracentesis
- Alcohol level/drug screen if suspicion arises based on history

Differential Diagnosis of HE

Overt HE or Acute Confusional State

- Diabetes
- Alcohol
- Drugs
- Neuroinfections
- Electrolyte disorders
- Nonconvulsive epilepsy
- Psychiatric disorders
- Intracranial bleeding and stroke
- Severe medical stress

Other Presentations

- Dementia
- Brain lesions
- Obstructive sleep apnea

Vilstrup H, et al. *Hepatology*. 2014;60(2):715-735.

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Treatment of Acute Overt HE

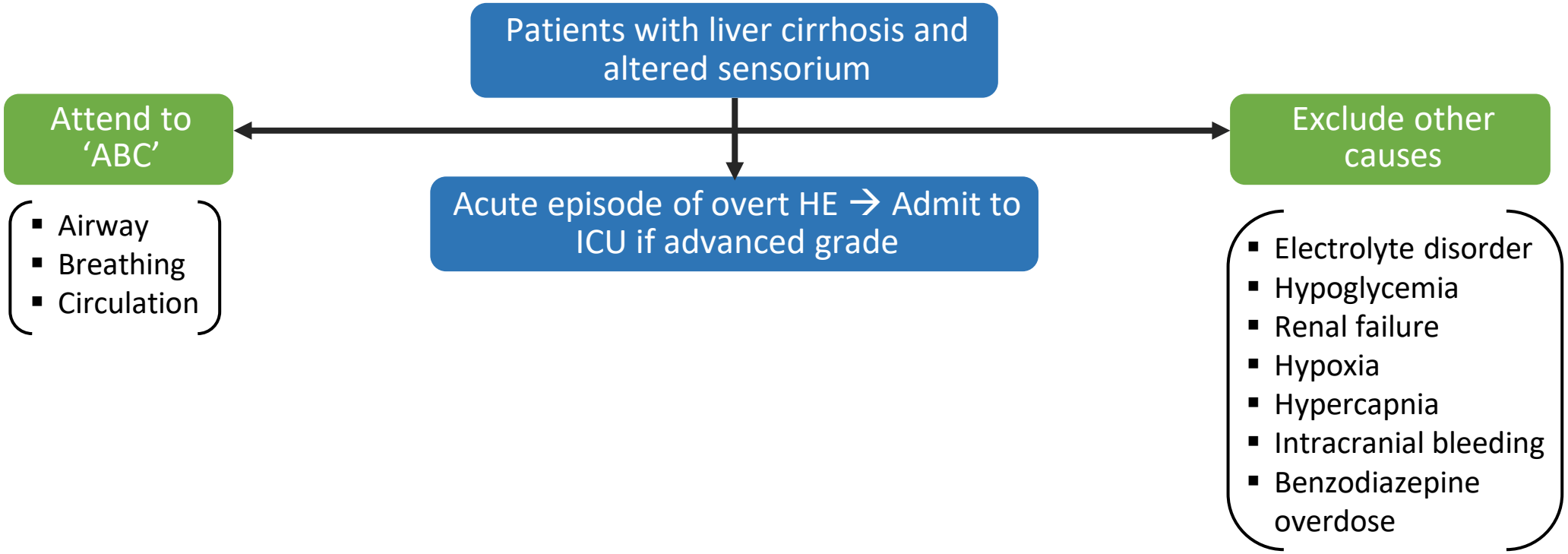
Approach to the Management of Overt HE (2014 AASLD/EASL)

AASLD, American Association for the Study of Liver Disease; EASL; European Association for the Study of the Liver.
Vilstrup H, et al. *Hepatology*. 2014;60(2):715-735.

Algorithm for the Management of Overt HE (2020 ISHEN Consensus)

Patients with liver cirrhosis and altered sensorium

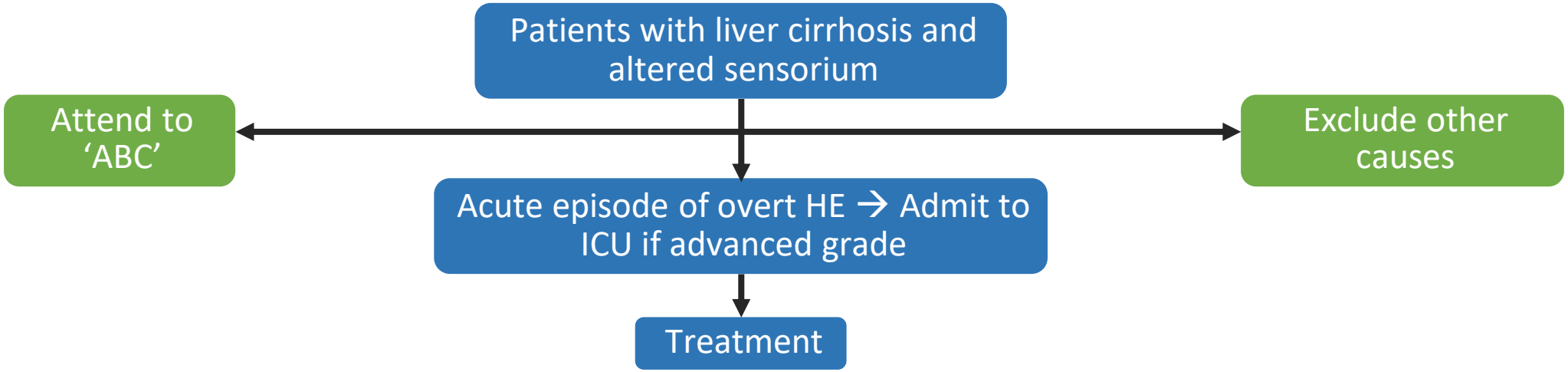
Algorithm for the Management of Overt HE (2020 ISHEN Consensus)



ICU, intensive care unit.

Bajaj JS, et al. *Am J Gastroenterol*. 2020;115(7):989-1002.

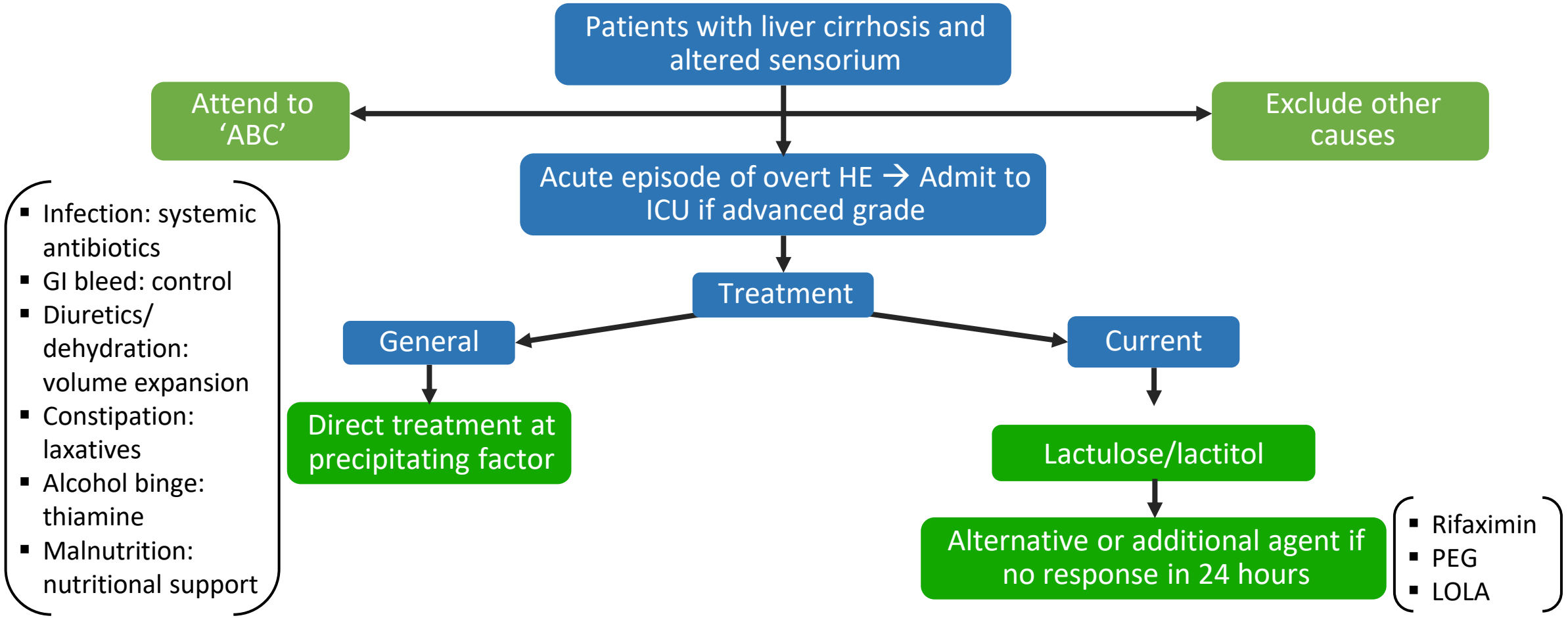
Algorithm for the Management of Overt HE (2020 ISHEN Consensus)



ICU, intensive care unit.

Bajaj JS, et al. *Am J Gastroenterol*. 2020;115(7):989-1002.

Algorithm for the Management of Overt HE (2020 ISHEN Consensus)



ICU, intensive care unit.

Bajaj JS, et al. *Am J Gastroenterol*. 2020;115(7):989-1002.

Therapies for Acute Overt HE

	Agent	Mechanism of Action/Comments
Available	Nonabsorbable disaccharides	Promotes NH_3 conversion to NH_4^+ in the colon, shifting flora from urease- to non-urease-producing bacteria; exerts a cathartic effect
	Rifaximin	Reduces NH_3 by eliminating NH_3-producing colon bacteria; indicated for reducing risk of OHE recurrence in adults
	Zinc	Enhances urea formation from NH_3 and amino acids
Emerging	PEG 3350-electrolyte solution	Purgative; causes water to be retained in the colon, produces a watery stool
	Ornithine Phenylacetate	Ammonia scavenger; lowers ammonia levels independent of gut action (ie, by a different mechanism) in patients with cirrhosis

NH4, ammonium; OHE, overt hepatic encephalopathy.

Elwir S, et al. *J Clin Transl Hepatol*. 2017;5(2):142-151; Flamm SL. *Ther Adv Gastroenterol*. 2011;4(3):199-206; Lynn AM, et al. *Liver Transpl*. 2016 Jun;22(6):723-31; Leise MD, et al. *Mayo Clin Proc*. 2014;89(2):241-253.

Lactulose for the Reduction of NH3 in Patients With OHE

Dosing

- Initial dose: 30 mL orally, TID
- 300 mL in 700 mL water or normal saline as an enema retained for 30–60 minutes every 4–6 hours

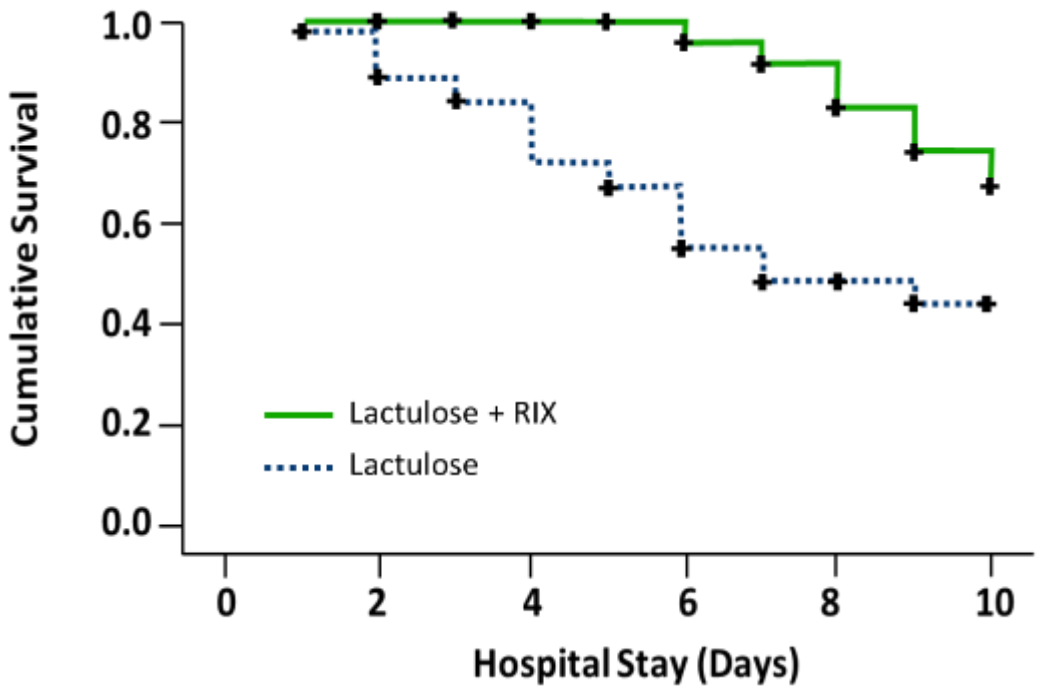
Adverse events (AEs)*

- Aspiration
- Dehydration
- Hypernatremia
- Severe perianal skin irritation
- Precipitation of HE with overuse

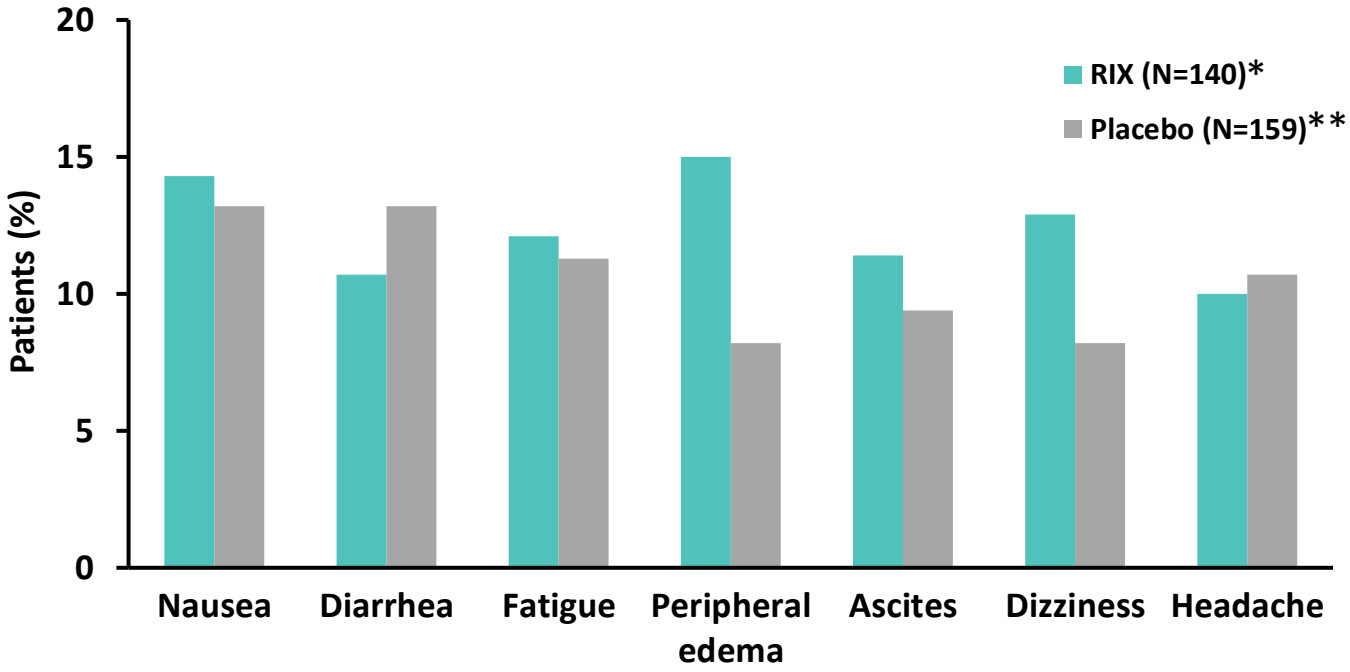
*Data for precise frequency of AEs are not available.
TID, three times a day.
Enulose® [package insert]. Baltimore, MD: Actavis Mid Atlantic LLC; 2006; Vilstrup H, et al. *Hepatology*. 2014;60(2):715-735.

Rifaximin (RIX) Added on to Lactulose for the Treatment of Acute Overt HE

Survival



Safety and Tolerability

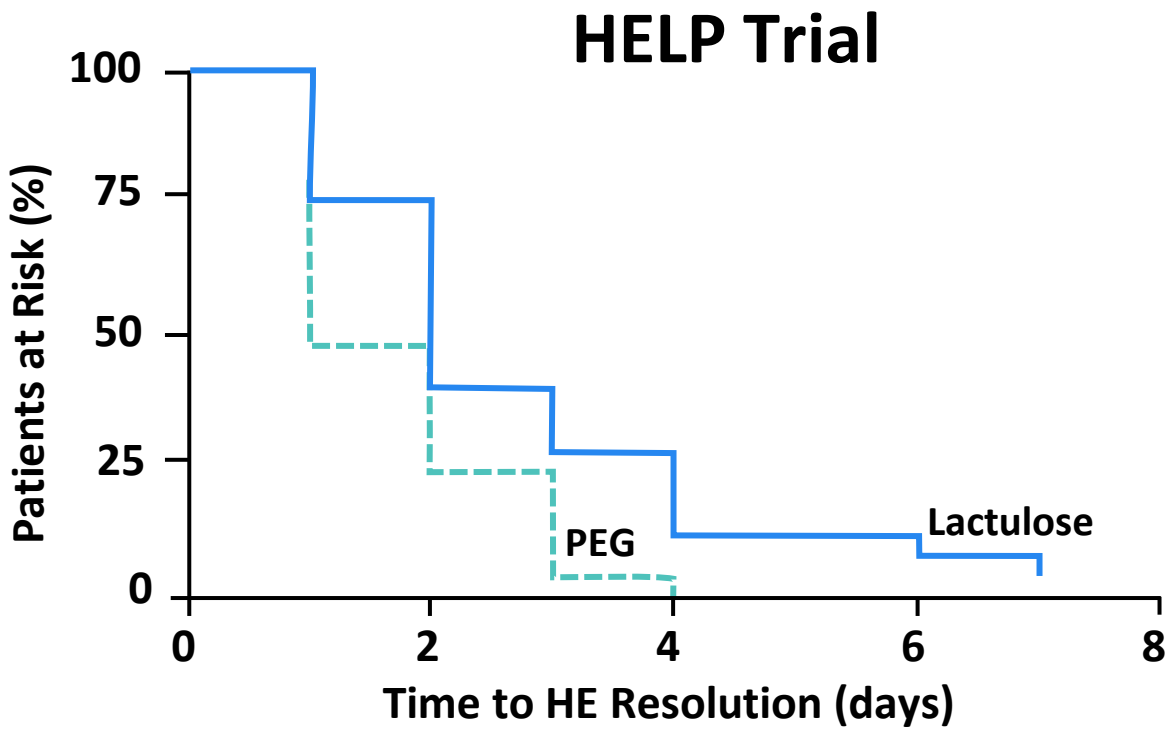


The incidence of common AEs† did not differ significantly between groups.

*91.4% receiving concomitant lactulose; ** 91.2% receiving concomitant lactulose; †AEs occurring at an incidence rate of ≥10% in the rifaximin group.

Bass NM, et al. *N Engl J Med*. 2010;362(12):1071-1081; Sharma BC, et al. *Am J Gastroenterol*. 2013;108(9):1458-1463.

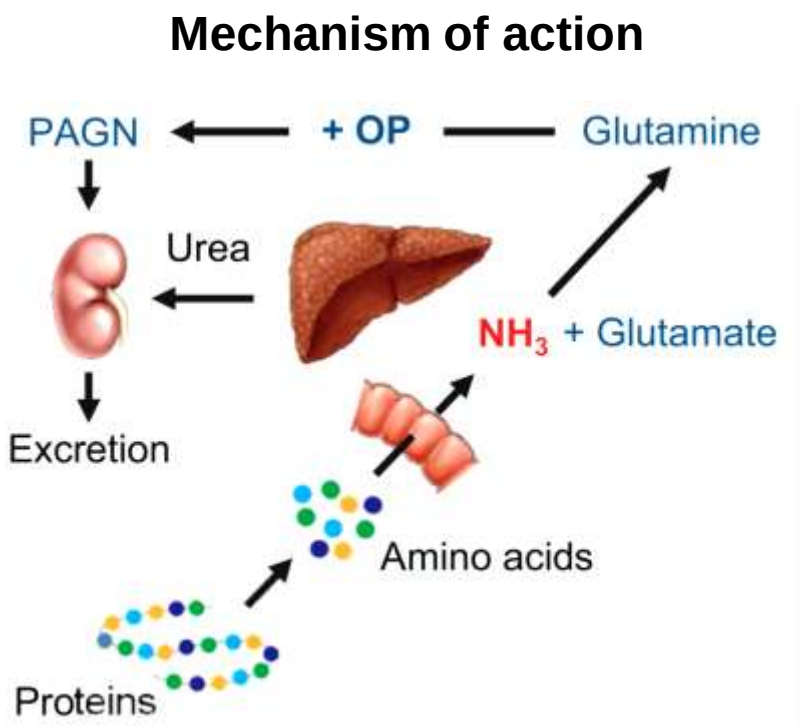
PEG-3350 Treatment in Patients With Cirrhosis Hospitalized for HE

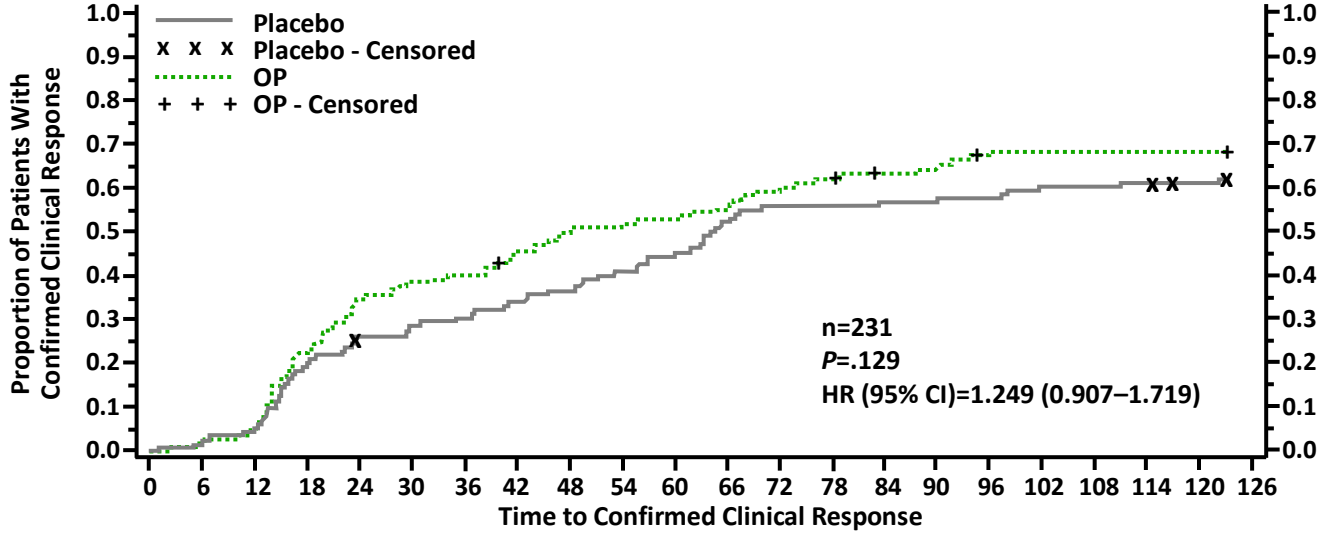


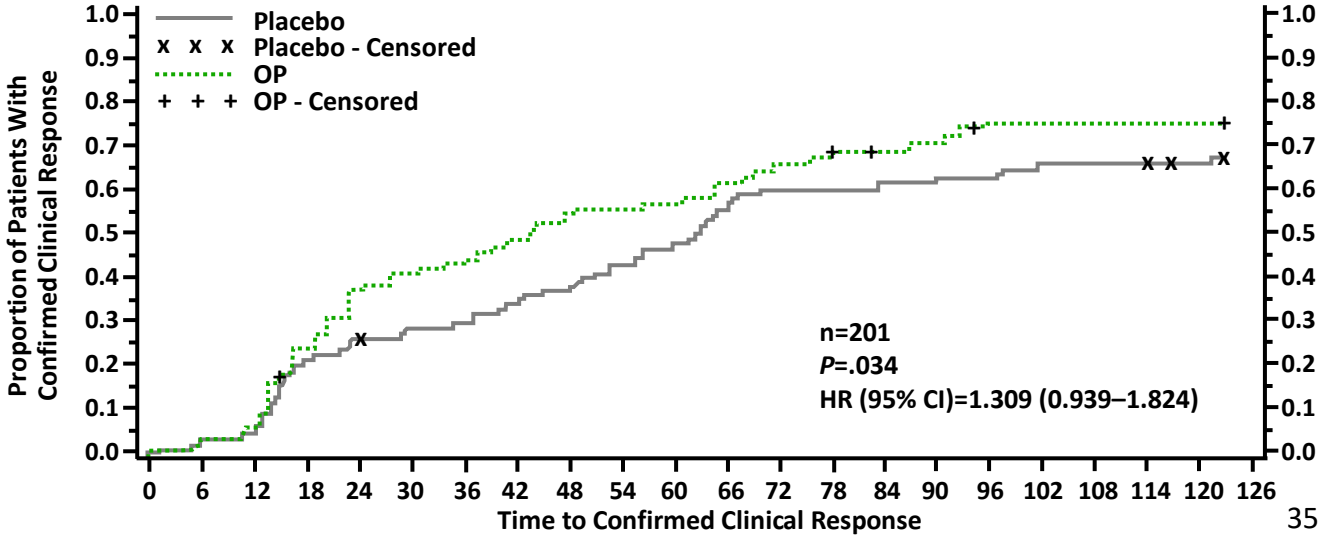
- PEG vs standard lactulose increased:
  - **Rate of HE resolution**‡ (*graph*)
  - % patients with **HESA score improvement ≥1***
  - Mean **HESA score at 24 hours**†

*P <.01; †P=.002; ‡P=.01.
HESA, hepatic encephalopathy scoring algorithm.
Rahimi RS, et al. *JAMA Int Med*. 2014;174(11):1727-1733.

Ornithine Phenylacetate in Hospitalized Patients With Cirrhosis, Increased Ammonia Levels, and Acute OHE







OP, ornithine phenylacetate; PAGN, phenylacetylglutamine.

Rahimi RS, et al. *Clin Gastroenterol Hepatol*. 2020;S1542-3565(20)31432-31434.

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Prophylaxis of Recurrent Overt HE

Indications for HE Prophylaxis

EASL Guidelines 2022

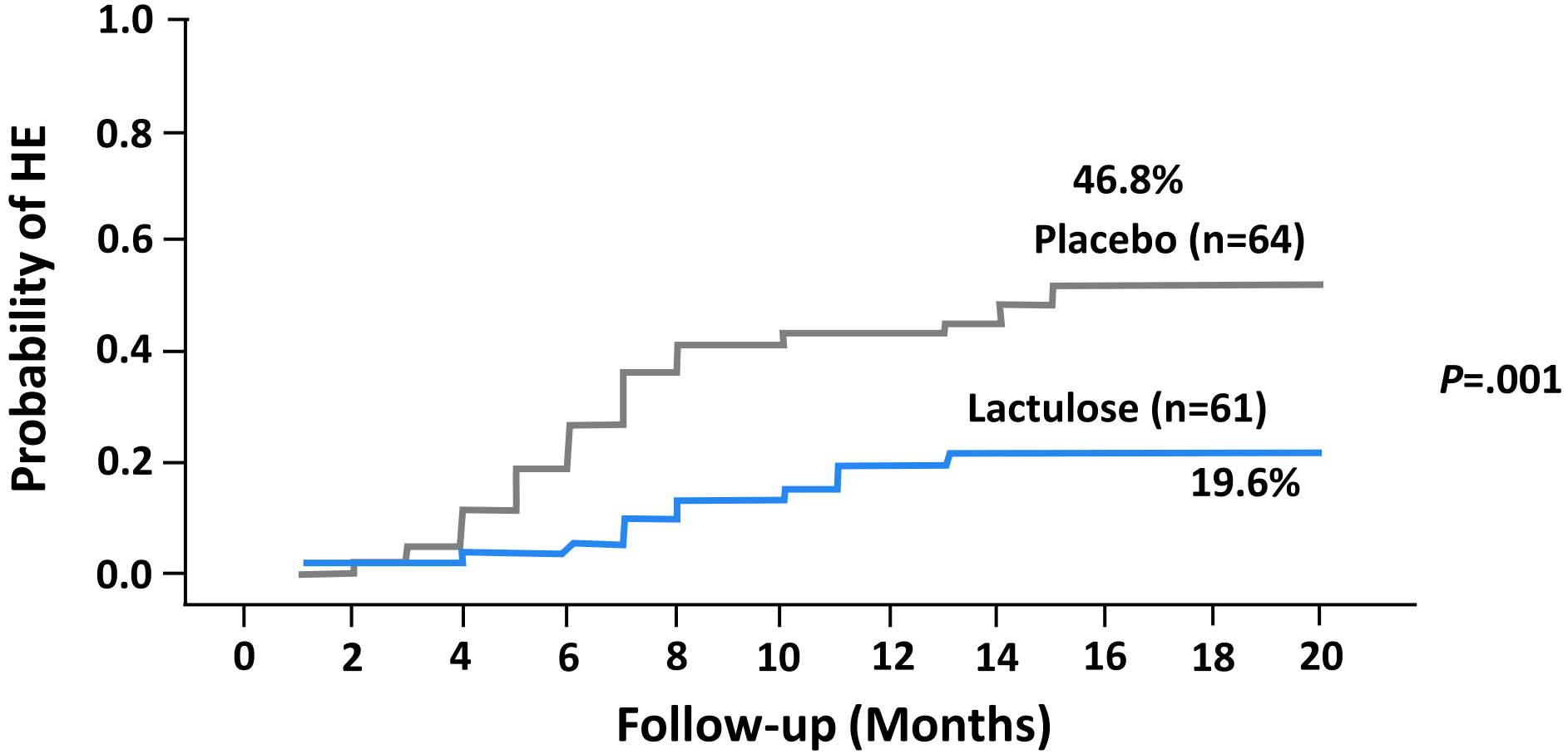
- Lactulose is recommended as secondary prophylaxis following a first episode of overt HE, and should be titrated to obtain 2-3 bowel movements per day (Strong recommendation, 96% consensus).
- Rifaximin as an adjunct to lactulose is recommended as secondary prophylaxis following ≥1 additional episodes of overt HE within 6 months of the first one

AASL and EASL Guidelines 2014

- Lactulose is recommended for prevention of recurrent episodes of HE after the initial episode
- Rifaximin as add-on to lactulose is recommended for prevention of recurrent episodes of HE after the second episode

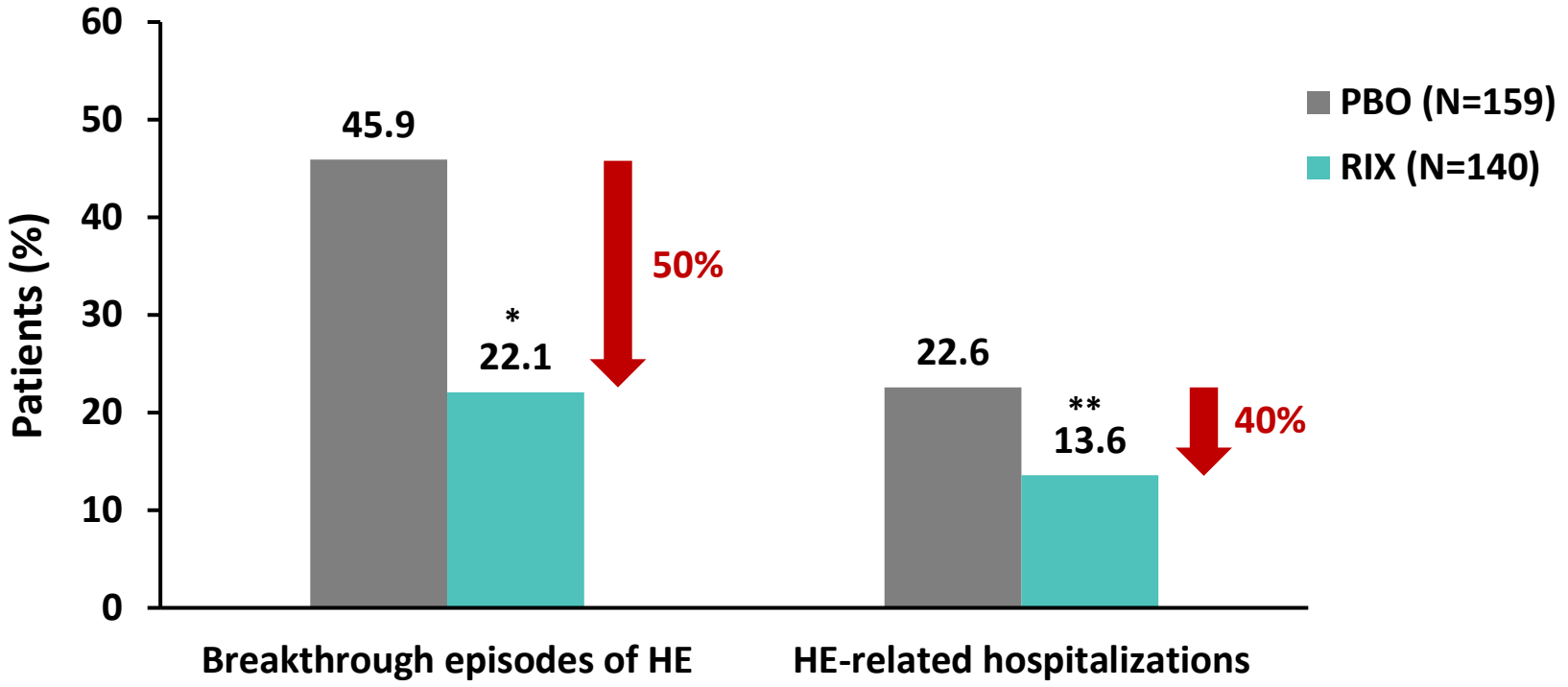
European Association for the Study of the Liver (EASL). June 17, 2022. DOI:https://doi.org/10.1016/j.jhep.2022.06.001
American Association for the Study of Liver Disease (AASLD) Practice Guideline. Available at: https://www.aasld.org/sites/default/files/2022-07/Hepatic%20Encephalopathy%20in%20Chronic%20Liver%20Disease%202014.pdf

Lactulose Prevents Recurrence of HE in Patients With Cirrhosis



Sharma BC, et al. *Gastroenterology*. 2009;137(3):885-891.e881.

Effect of RIX on Breakthrough HE Episodes and HE-Related Hospitalizations



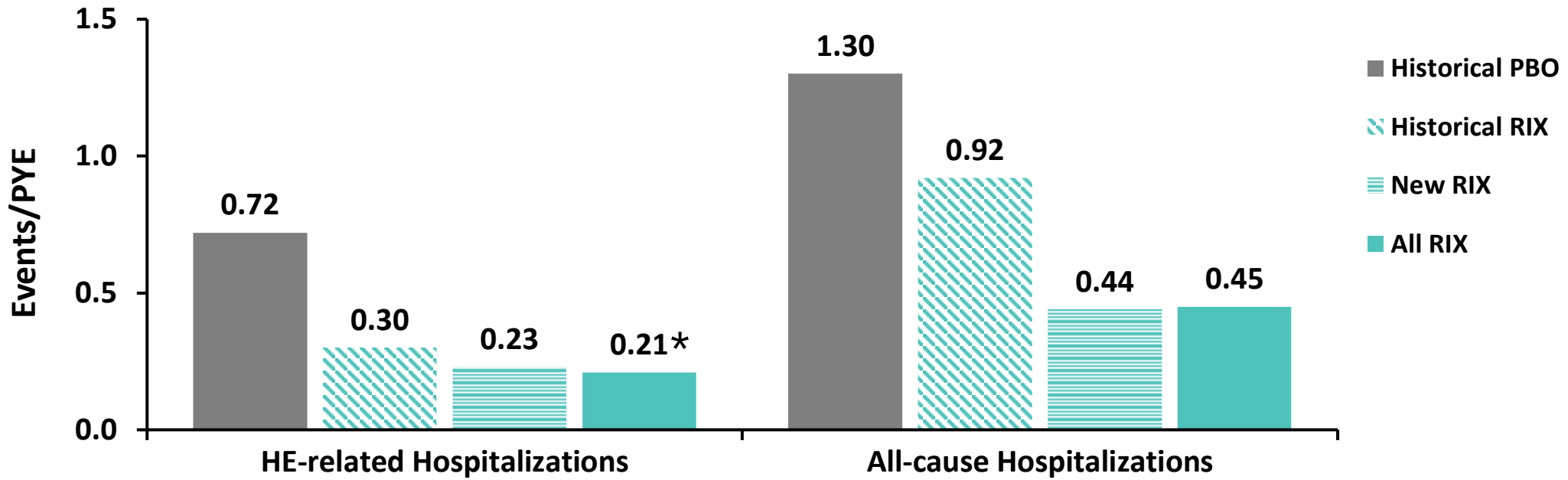
Over a 6-month period, treatment with RIX resulted in lower rates of both OHE breakthrough and HE-related hospitalizations vs PBO.

*P <.001 vs PBO; **P=.01 vs PBO.

Note: >90% of patients received concomitant lactulose during the study period.

Bass NM, et al. *N Engl J Med*. 2010;362(12):1071-1081.

Long-term Maintenance of Remission From Overt HE With RIX



Treatment with RIX for ≥2 years reduced the rate of HE-related and all-cause hospitalization, without increasing AE rates.

*P <.001 vs PBO.

PYE, person-years of exposure.

Mullen KD, et al. *Clin Gastroenterol Hepatol*. 2014;12(8):1390-1397.e1392.

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Transition of Care Following Acute OHE Resolution

Planning for Patient Discharge

Neurological Status

- Confirm status
- Assess other contributing causes
- Inform caregivers of potential changes after acute illness resolution and need for monitoring

Patient & Caregiver Education

- Identify and discuss precipitating factors
- Plan for future HE management
  - Role of nutrition
  - Importance of prophylaxis
  - Driving considerations
  - Recommended vaccinations

Postdischarge Follow-up

- Ensure follow-up with PCPs who can:
  - ✓ Adjust prophylactic treatment
  - ✓ Advise on avoiding precipitating factors
  - ✓ Act as liaison between patient's family, caregivers, and HCPs
- Discuss GI consult

HCP, healthcare provider; PCP, primary care provider.

Vilstrup H, et al. *Hepatology*. 2014;60(2):715-735.

Precipitants of HE in Patients With Cirrhosis

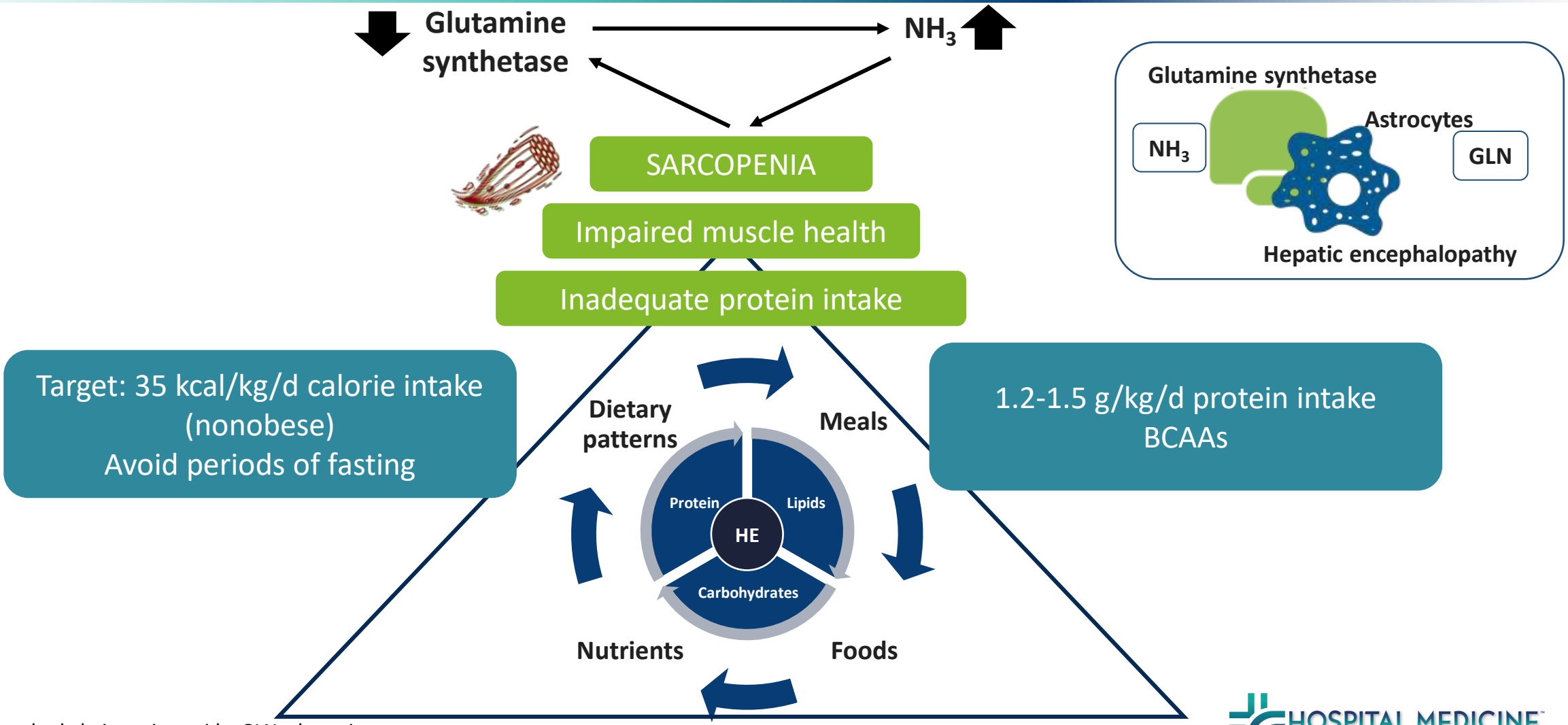
- Acute renal failure
- Constipation
- Dehydration
- Electrolyte imbalances (eg, hypokalemia [potassium < 3.5 mmol/L]; hyponatremia [sodium < 130 mEq/L])
- GI bleeding
- High-protein diet
- Infections (eg, abdominal infection, bacteremia, cellulitis, respiratory infection, SBP, UTI)
- Lactulose nonadherence
- Large-volume paracentesis
- Medications (eg, benzodiazepines, opioids)
- Acute portal vein thrombosis
- Spontaneous portosystemic shunts
- TIPS

Dehydration (46%-76%), acute kidney injury (32%-76%), lactulose nonadherence (about 50%), constipation (about 40%), and infections (20%-42%) were the most frequently identified precipitants for hospitalization in retrospective and prospective groups (n=149 patients in retrospective group and n=45 in prospective group)

SBP, spontaneous bacterial peritonitis; UTI, urinary tract infection.

Pantham G, et al. *Dig Dis Sci*. 2017;62:2166-2173.

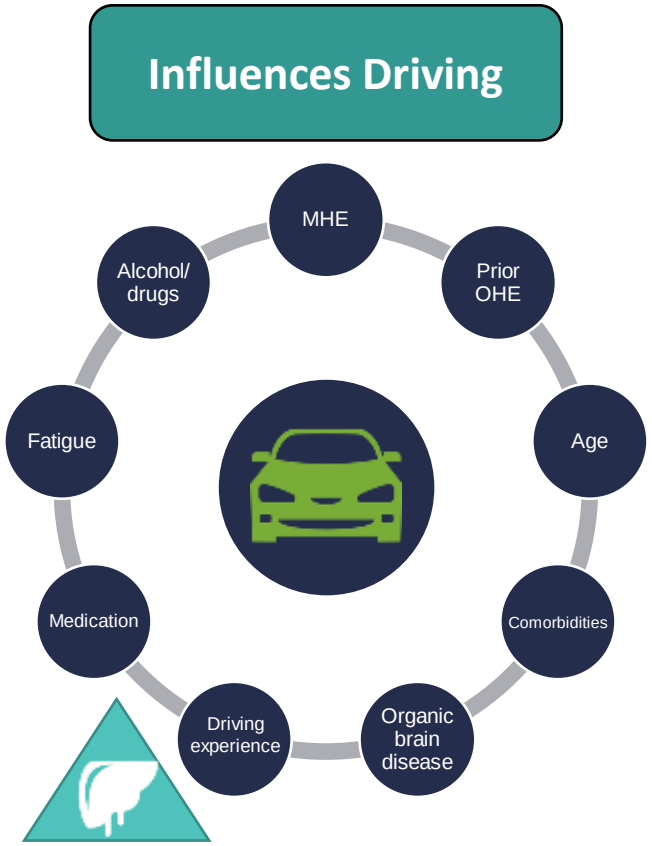
The Central Role of Nutrition in HE Management



BCAA, branched-chain amino acids; GLN, glutamine.

Bajaj JS, et al. *Am J Gastroenterol*. 2020;115:989-1002.

Contributing Factors, Consequences, and Management of Driving Impairment in HE



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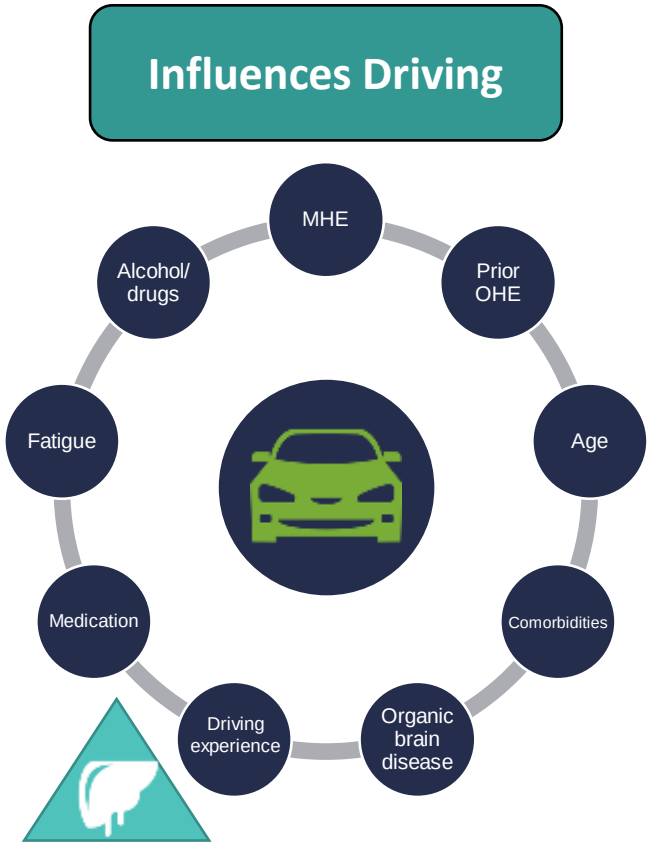

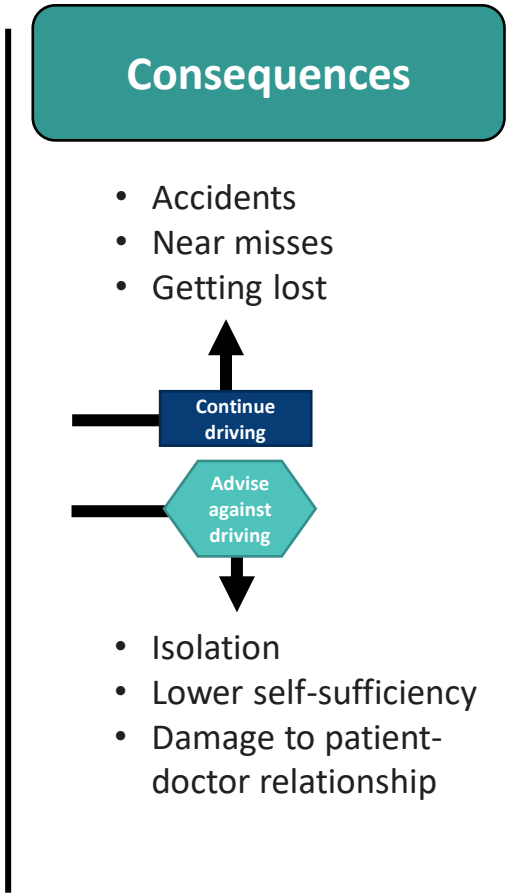

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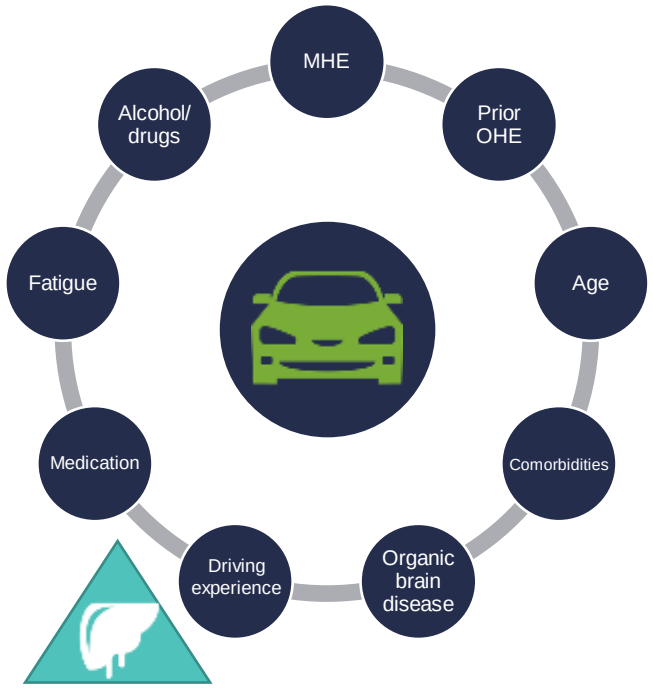
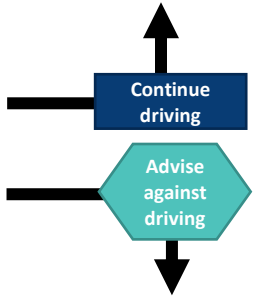
Contributing Factors, Consequences, and Management of Driving Impairment in HE

Influences Driving



Consequences

- Accidents
- Near misses
- Getting lost



- Isolation
- Lower self-sufficiency
- Damage to patient-doctor relationship

Driving Assessment

- Short driving history should be taken at every visit
- On-road driving test
- Driving simulation
- Driving history
- Cognitive testing

CAUTION

- Physicians do not have legal authority to withdraw a patient's driver license
- Physicians may be obliged to report an unsafe driver to authorities

Bajaj JS, et al. *Am J Gastroenterol*. 2020;115:989-1002.

Contributing Factors, Consequences, and Management of Driving Impairment in HE

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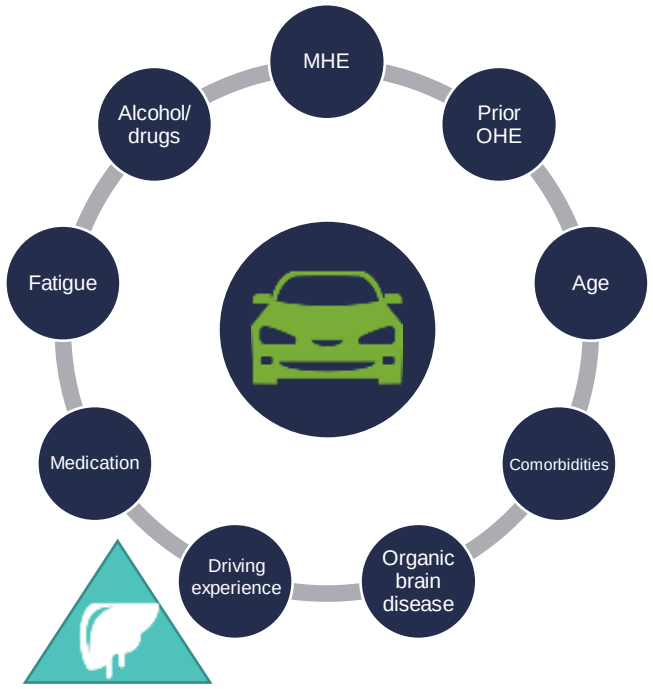

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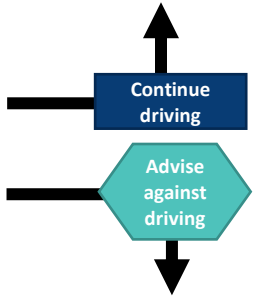

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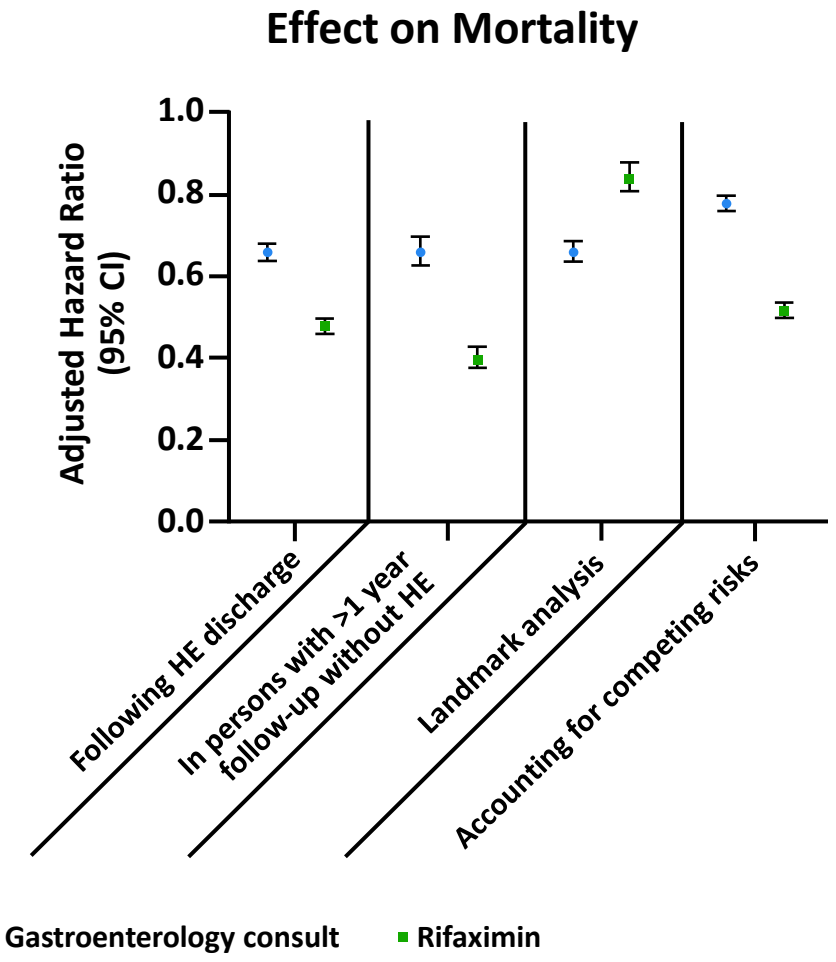
Management

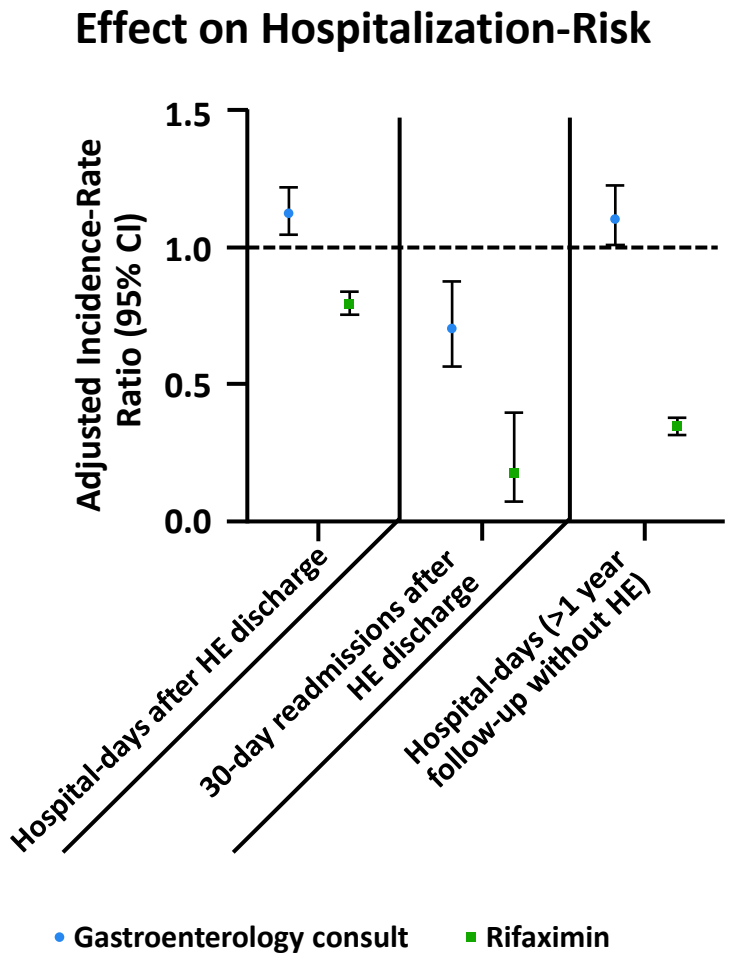
- Advise patients not to drive ~3 months after the last overt HE episode
- No evidence to support a driving ban to all with CHE/MHE without prior overt HE, also take driving history into account
- Initiate or optimize HE treatment
- Avoid/withdraw/decrease sedative medications
- Optimize treatment of comorbid diseases
- Refer to authorities for formal testing for resuming driving privileges

CHE, covert hepatic encephalopathy.

Bajaj JS, et al. *Am J Gastroenterol*. 2020;115:989-1002.

Impact of Combination Lactulose-Rifaximin and GI Consultation on Postdischarge Outcomes in Patients With HE





Tapper EB, et al. *Aliment Pharmacol Ther*. 2020;51:1397-1405.

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Case Study Evaluations

Case Patient 1: Henry

A 52-year-old man with a history of cirrhosis presents to the ED for severe, diffuse abdominal pain over the past 3 to 4 days. According to his wife, he has developed mental status changes accompanied by nausea and vomiting over the past 24 hours. He denies having a sore throat, chest pain, myalgia, or anosmia. Physical exam reveals shortness of breath and a temperature of 99.6º. Testing reveals elevated LFTs. The patient demonstrates a mild cough, but otherwise normal respiratory exam. His chest x-ray is unremarkable.

ED, emergency department; LFTs, liver function tests.

Case #1: Discussion Question

Which of the following tests would be of little prognostic value in the patient assessment?

A. Ammonia levels
B. Serum electrolytes
C. Blood cultures
D. PCR test for COVID-19

PCR, polymerase chain reaction.

Case #1: Discussion Question

What is your next course of action for this patient?

A. Provide supportive care for unconscious patients
B. Identify and address precipitating factors for HE
C. Initiate empirical HE treatment
D. Evaluate alternative causes of HE symptoms
E. All of the above

Case Patient 2: Gina

A 68-year-old woman with a history of cirrhosis and recurrent OHE presents with an acute episode of HE. The patient lives with her daughter and son-in-law, who report that she has been sleeping more than usual over the past two days. The patient is stuporous and lethargic, and her responses to questions are delayed. She doesn't appear to know what day it is or where she is.

The patient is currently being treated with lactulose. When asked about adherence to her maintenance therapy, her daughter responds that she is generally reluctant to change any eating-related behaviors and complains constantly about the GI side effects of the lactulose.

Case #2: Discussion Question

Once the current HE episode is resolved, what changes (if any) to the patient's prophylactic therapy would you recommend?

A. No change
B. Adjust the patient's dose of lactulose
C. Prescribe rifaximin as add-on therapy
D. Prescribe PEG as an alternative

Case #2: Discussion Question

Prior to leaving the hospital, the patient asks about restrictions on driving. How long would you advise the patient to wait before driving again?

A. 6 weeks
B. 2 months
C. 3 months
D. 6 months

Summary

- HE is a major complication of liver disease that represents a substantial healthcare burden in the hospital setting
- HCPs should be aware that patients with cirrhosis and COVID-19 may present with signs of HE and are at heightened risk for poor health outcomes including death
- Management goals include active treatment of acute episodes, prevention of recurrence, and evaluation for surgical intervention
- Several agents have shown good efficacy when administered as acute treatment or secondary prophylaxis
- Following an acute episode of HE, prophylaxis, patient education, and follow-up are essential to prevent recurrence and hospitalization, and to improve health outcomes

Clinical Pearls

- For patients with decompensated liver disease, obtain a thorough history of mental status changes, rule out other causes of neurological disturbances, and evaluate the need for HE treatment
- Utilize complementary strategies for ammonia reduction, supportive care, and nutritional support for the treatment of acute overt HE
- Consider secondary prophylaxis with lactulose and/or rifaximin in patients with previous overt HE episodes and at high risk for rehospitalization
- Assess the nutrition of all patients with cirrhosis and HE, and encourage an individualized plan for maintaining adequate intake of calories, fiber, and micronutrients

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Thank you!

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