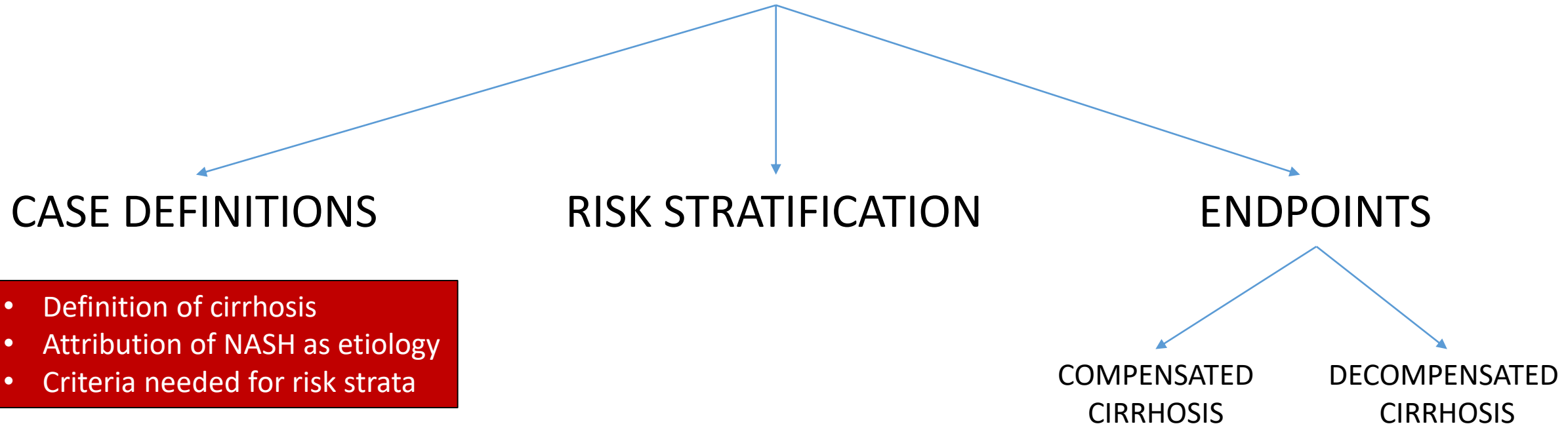


Liver Forum Cirrhosis Working Group Report

CIRRHOSIS WORKING GROUPS



Diagnosis of cirrhosis

- Histological definition (WHO):
 - architectural disruption
 - regenerative nodules
 - Fibrosis with circumscription of regenerative nodules

Definition of cirrhosis for NASH trials

- The presence of cirrhosis may be inferred from noninvasive parameters (Recommendation 1, Evidence B):
- A: HVPG ≥ 7 mmHg or
- B: When one of the following measures of liver stiffness is present
 - VCTE LSM > 15 kp, MRE LSM > 6.7 Kpa *Along with*
 - Imaging or endoscopic evidence of collaterals or splenomegaly without portal vein thrombosis, **Or both** of the following
 - AST : ALT > 1 but < 2
 - Platelet count $< 150,000/\text{mm}^3$
- The potential error in VCTE or MRE in distinguishing F3 vs F4 is minimized by additional findings of portal hypertension

Definite NASH- (in context of cirrhosis)

- Histological evidence of cirrhosis- extensive architectural disruption, development of fibrosis with circumscription of regenerative nodules
- Features of steatohepatitis-
 - steatosis
 - hepatocellular ballooning
 - inflammation
- Nonalcoholic nature of disease established by clinical assessment, AUDIT

Category 1: Definite NASH- (in context of cirrhosis)

- A. Histological description of cirrhosis and steatohepatitis
- B. Patients with previous biopsy showing steatohepatitis, but now with evidence of cirrhosis, either by a clinical picture or imaging, or biopsy.
 - When cirrhosis is diagnosed by clinical-imaging means, there should be at least one or more risk factors for NAFLD at the time of entry
- C. Patients with current biopsy showing cirrhosis and steatosis only.
 - 2 or more features of metabolic syndrome
 - Type 2 diabetes (there was no consensus on duration- a 5 yr duration recommended by FDA)

• ABSENCE OF OTHER CAUSES OF CIRRHOSIS

Category 2: Probable NASH- in a patient with cirrhosis

- A. patients with a previous biopsy showing steatosis, but now with cirrhosis, either by a clinical picture, imaging, or biopsy.
 - Need 2 or more features of metabolic syndrome
- B. Patients with cirrhosis with current or previous imaging showing steatosis.
 - Need 2 or more features of metabolic syndrome
- C. patients with “cryptogenic cirrhosis” without current or previous evidence of steatosis by imaging or steatosis/steatohepatitis by histology.
 - Need 2 or more features of metabolic syndrome

• ABSENCE OF OTHER CAUSES OF CIRRHOSIS

Category 3: Possible NASH- in a patient with cirrhosis

- A. cryptogenic cirrhosis” patients without current or previous evidence of steatosis by imaging or steatosis/steatohepatitis by histology.
 - Need 2 or more features of metabolic syndrome
- B. Patients with previously eradicated hepatitis C virus, or a remote history of heavy alcohol consumption, but who currently have evidence of cirrhosis and histological evidence of steatohepatitis. Patients with a remote history of heavy alcohol consumption should not have evidence of cirrhosis at the time of stopping alcohol.