The noninvasive point of care MBT accurately predicts decompensation events better than MELD in compensated (MELD <15) NASH cirrhotics

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INTRODUCTION

Patients with compensated non-alcoholic steatohepatitis (NASH) cirrhosis are at risk for developing decompensation (ascites, variceal bleeding or hepatic encephalopathy (HE)), the main determinant of survival. A Model for End Stage Liver Disease (MELD) score has been shown to be predictive of decompensation.

The 13C-Methacetin Breath Test (MBT) using the Exalenz BreathID® System, is a non-invasive, real-time molecular correlation spectroscopy assay that quantitates hepatic cytochrome P450 1A2 metabolism of ingested non-radioactive 13C-labeled methacetin by measuring the changes in the 13C/12C ratio in expired breath.

The MBT measures a relevant liver metabolic function that reflects overall liver function.

AIM

To evaluate the MBT’s ability to predict decompensation in compensated NASH cirrhosis.

MATERIAL & METHODS

MBT was performed on 160 patients with compensated NASH cirrhosis (i.e. no prior variceal hemorrhage, ascites or HE). All were followed prospectively for decompensation (maximal number of days=508).

RESULTS

Of the 160 patients enrolled, 15 were excluded due to MBT protocol violations and 1 for missing MELD, leaving 144 patients for analysis. Their baseline characteristics can be seen in Table 1.

Twelve patients (8%) developed a first decompensating event during the study (Table 2), of which the MBT identified 10.

The mean baseline PDR-Peak for the 12 patients with a decompensation event was 16.3%/h±11.5 (SD) and the mean baseline MELD was 7.7±1.4 (SD).

When setting cutoffs at median values: 21%/h for PDR-Peak and 7 for MELD (see Figure 1):

- The hazard ratio (HR) for decompensation for the PDR-Peak was significant at 5.71 (95%CL: 1.24, 26.21; p=0.025).
- The HR for decompensation for MELD was not significant at 2.3 (95%CL: 0.6188, 8.5179; p=0.214).

CONCLUSION

MBT, which measures liver function, strongly predicts liver decompensation in patients with compensated NASH cirrhosis.

The data suggest that this safe, valid, operator-independent, non-invasive point-of-care tool may be a more effective clinical tool than currently used tools to help identify patients at increased risk for hepatic decompensation.

DISCLOSURES

The studies were sponsored by Galectin Therapeutics Inc. and Exalenz Bioscience Ltd.

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