

# 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 <sup>13</sup>C-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 <sup>13</sup>C-labeled methacetin by measuring the changes in the <sup>13</sup>C/<sup>12</sup>C 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).

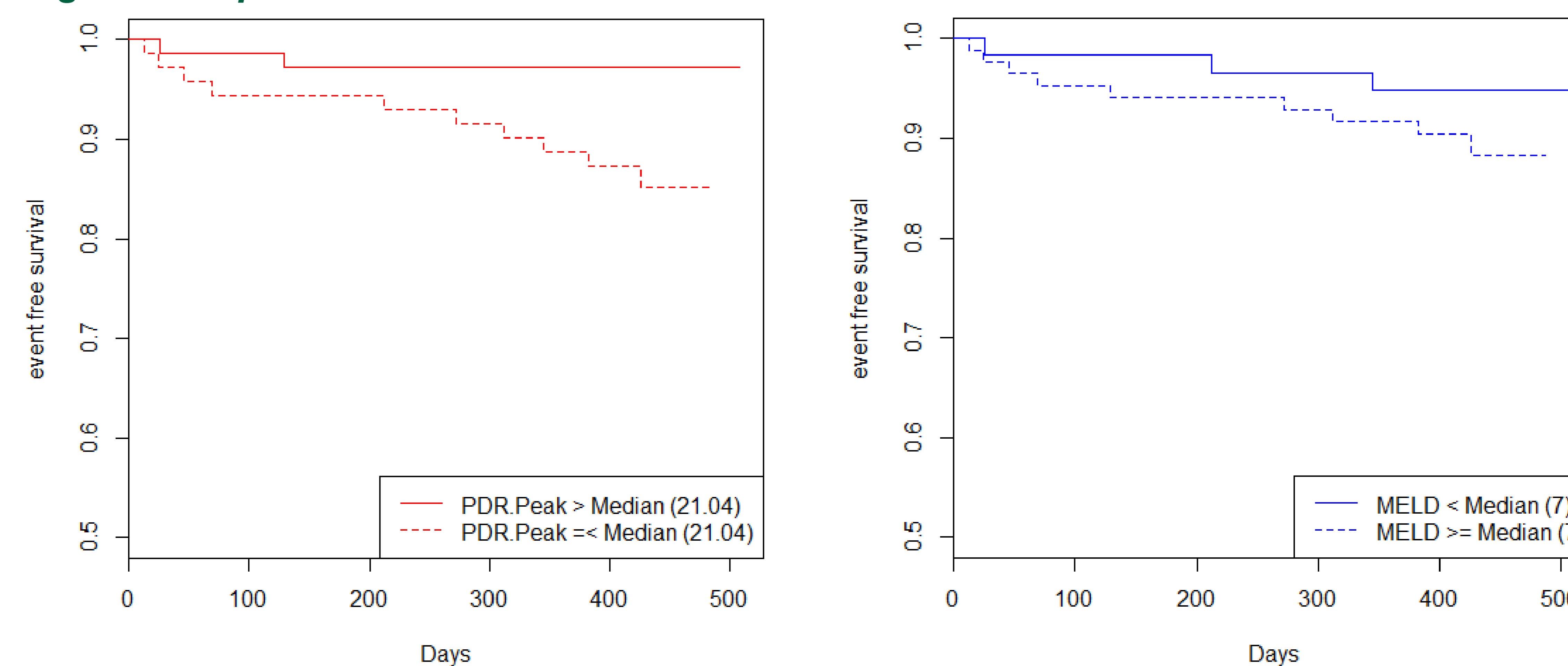
**Table 1: Baseline characteristics of analyzed patient population**

Patient Population (n=144)	
Females (%)	67%
Average Age (SD) years	59 (8.5)
Average BMI (SD) kg/m <sup>2</sup>	34.7 (6.3)
Average MELD (SD)	7.3 (1.6)
Average PDR-Peak (SD) %/h	22.2 (9.5)

**Table 2: 1<sup>st</sup> decompensation event**

1 <sup>st</sup> Decompensation event	n=12
Ascites	2
Variceal Hemorrhage	2
Gastropathy Hemorrhage	2
Hepatic Encephalopathy	6

**Figure 1: Kaplan Meier Plot with both MBT and MELD hazard ratios**



## 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.**

**Figure 2: The BreathID® Breath Test**



## DISCLOSURES

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

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