

# CLINICAL CHARACTERISTICS AND OUTCOMES OF PATIENTS WITH PRESUMED MASLD WHO MEET METALD CRITERIA IN THE TARGET-NASH COHORT

A. BARRITT IV<sup>1</sup>, E. GREENE<sup>1</sup>, A. MOSPAN<sup>2</sup>, B. MUNOZ-HERNANDEZ<sup>2</sup>, H. MORRIS<sup>2</sup>, R. LOOMBA<sup>3</sup>, V. WONG<sup>4</sup>, B. NEUSCHWANDER-TETRI<sup>5</sup>, A. SANYAL<sup>6</sup>, on behalf of the TARGET-NASH Investigators

1. University of North Carolina, Chapel Hill, North Carolina, USA, 2. Target RWE, Durham, North Carolina, USA, 3. University of California, San Diego, La Jolla, California, USA, 4. Chinese University of Hong Kong, Hong Kong, 5. Saint Louis University, St. Louis, Missouri, USA, 6. Virginia Commonwealth University, Richmond, Virginia, USA



## INTRODUCTION

- Many patients with hepatic steatosis are presumed to have metabolic dysfunction associated steatotic liver disease (MASLD) due to comorbid cardiovascular (CV) risk factors. However, alcohol use may not be accurately quantified by providers or fully disclosed by some patients.

## AIM

- The characteristics and outcomes of patients with MASLD and increased alcohol intake (MetALD) are unknown. We sought to describe these patients in the TARGET-NASH cohort.

## METHODS

- Study participants were enrolled in the US TARGET NASH cohort which did not exclude moderate alcohol use from 2016 through 2024.
- Patients with MetALD were defined as those with an Alcohol Use Disorders Identification Test (AUDIT) score>7.
- Baseline demographic and clinical data were compared between the MetALD and MASLD groups. Hazard ratios were calculated for time to event analyses. Major adverse cardiovascular events (MACE), decompensation events, and cancer were the longitudinal outcomes of interest.

## RESULTS

- Overall, 4714 patients with ≥1 year follow-up were included in the analysis.
- Overall, AUDIT scores ranged from 0-23. The MetALD group had 124 (2.6%) patients with an AUDIT score > 7 (**Figure 1**).
- MetALD patients were younger (median 55 vs 59 years p = 0.05) and included more male (67% vs 39% p < 0.01) and non-Hispanic white (82% vs 73%) patients.
- MetALD patients were more likely to be current tobacco users (p < 0.01).
- Five patients denied alcohol use yet had AUDIT scores > 7.
- A smaller proportion of MetALD patients had diabetes, obesity, and prevalent CV disease (all p < 0.05).
- There were no differences in incident MACE between MetALD (4.8%) and MASLD (6.9%) patients, however, MetALD patients experienced these events sooner than MASLD patients (median time to event 71 months vs 79 months, p = 0.02).
- A smaller proportion of patients with MetALD had cirrhosis at index.
- The Hazard Ratios for decompensation events and incident cancers were not statistically significant when controlling for liver disease severity.

Figure 1. AUDIT Score distribution

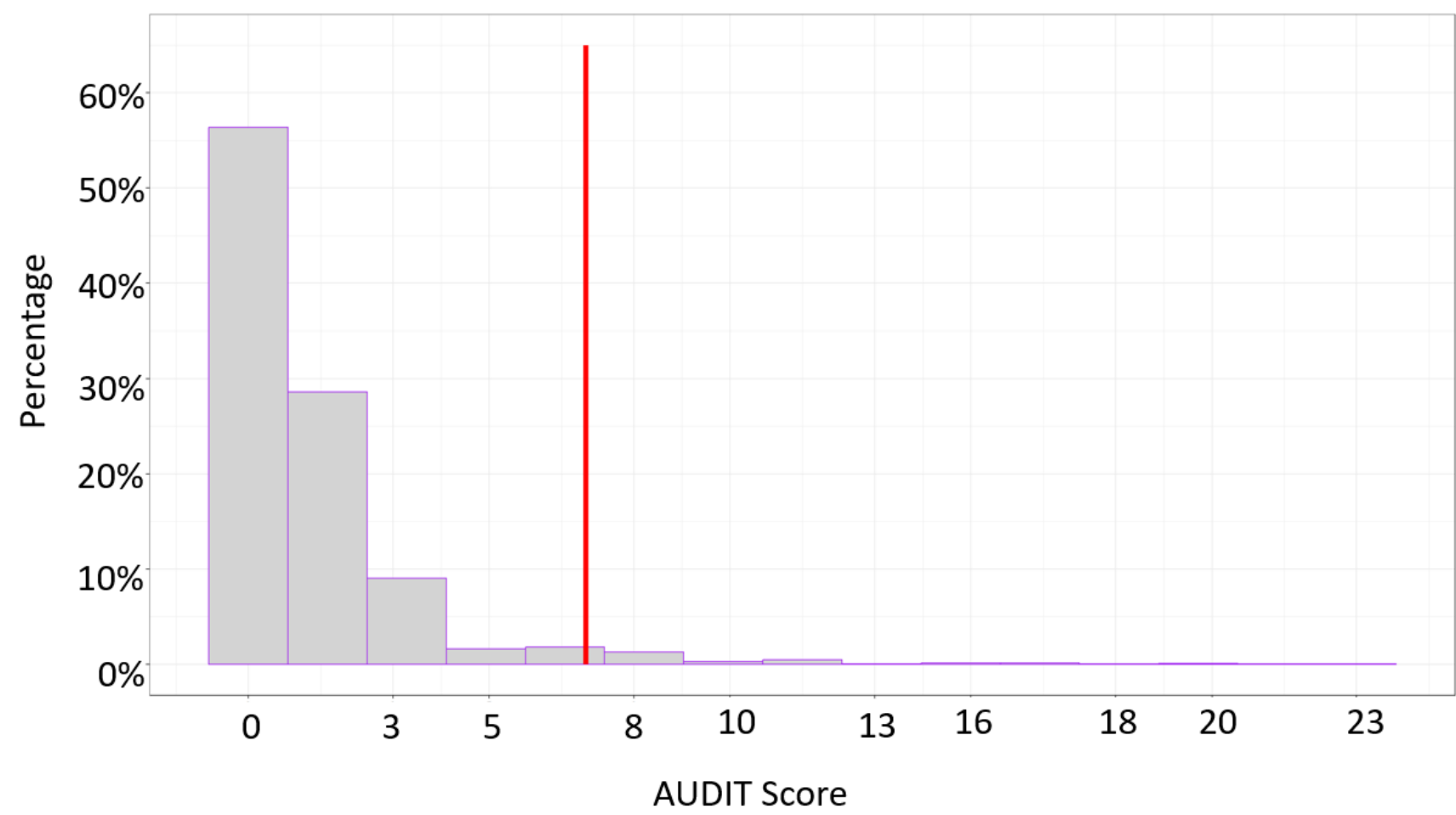


Table 1. Patient Characteristics at Enrollment

Patient Characteristics	MetALD (N = 124)	MASLD (N = 4590)	p-value
Age (years) Median (range)	55.0 (24 - 83)	59.0 (18 - 91)	0.05
Sex, n (%) Male	83 (66.9%)	1782 (38.8%)	<.01
Race- Ethnicity, n (%) Non-Hispanic White	101 (81.5%)	3338 (72.7%)	0.15
BMI (kg/m <sup>2</sup> ) at enrollment Mean (SD)	31.8 (5.70)	34.1 (7.47)	<.01
Insurance Type, n (%) Private Medicaid Medicare	90 (72.6%) 5 (4.0%) 28 (22.6%)	2750 (59.9%) 327 (7.1%) 1336 (29.1%)	0.02
Alcohol use at enrollment, n (%) Former Current Never Not reported	9 (7.3%) 92 (74.2%) 5 (4.0%) 18 (14.5%)	326 (7.1%) 1405 (30.6%) 1871 (40.8%) 988 (21.5%)	<.01
Tobacco use at enrollment, n (%) Former Current Never Not reported	44 (35.5%) 22 (17.7%) 43 (34.7%) 15 (12.1%)	1151 (25.1%) 315 (6.9%) 2435 (53.1%) 689 (15.0%)	<.01

Chi-square or Fisher exact text used for p-values comparing categorical variables;  
Kruskal-Wallis test used for p-values comparing distribution of continuous variables.

Table 2. Comorbidities Prior to Enrollment

Comorbidities	MetALD (N = 124)	MASLD (N = 4590)	p-value
Type 2 Diabetes, n (%)	38 (30.6%)	2603 (56.7%)	<.01
Hypertension, n (%)	117 (94.4%)	4494 (97.9%)	<.01
Obesity, n (%)	68 (54.8%)	3287 (71.6%)	<.01
Dyslipidemia, n (%)	72 (58.1%)	2999 (65.3%)	0.09
Autoimmune diseases, n (%)	28 (22.6%)	1559 (34.0%)	<.01
Inflammatory diseases, n (%)	18 (14.5%)	1094 (23.8%)	0.02
Depression, n (%)	44 (35.5%)	1907 (41.5%)	0.18
Cardiovascular disease, n (%)	65 (52.4%)	2965 (64.6%)	<.01

Chi-square or Fisher exact text used for p-values.

Table 3. Incidence Proportion and Time to Clinical Events of Interest

Events Summary	MetALD (N = 124)	MASLD (N = 4590)	p-value
Disease severity, n (%) MASL MASH MASH-Cirrhosis	39 (31.5%) 77 (62.1%) 8 (6.5%)	1155 (25.2%) 2199 (47.9%) 1236 (26.9%)	<.01
MACE, number of events (incidence proportion)	6 (4.8%)	319 (6.9%)	0.36
Time to first MACE event (months) Median (range)	71.3 (0.1 - 128.0)	78.5 (0.0 - 132.1)	0.02
Decompensation, number of events (incidence proportion)	21 (16.9%)	1808 (39.4%)	<.01
Time to first decompensation event (months) Median (range)	65.9 (0.4 - 128.0)	55.2 (0.0 - 132.1)	<.01
Any cancer excluding skin cancer, number of events (incidence proportion)	17 (13.7%)	995 (21.7%)	0.03
Time to first cancer event (months) Median (range)	65.3 (0.2 - 128.0)	69.8 (0.0 - 132.1)	0.26

Time to event was calculated as the time from index date to the time to the first event, time to death, or time to last data available. Index date was defined as the first date when one of the cardio-metabolic criteria was met using all data available, including the 3-year retrospective data.

Chi-square or Fisher exact test were used for p-values comparing categorical variables and Kruskal-Wallis test was used for p-values comparing distribution of continuous variables. .

## CONCLUSIONS

- Among patients presumed to have MASLD, 124 (2.6%) had AUDIT scores >7 and were reclassified at MetALD for this analysis.
- Despite younger age and fewer metabolic risk factors, MetALD patients suffered a similar number of incident MACE events on a faster timeframe compared with traditional MASLD patients.
- It is critical for providers to address alcohol use among patents with presumed MASLD to accurately risk stratify adverse events.

## ACKNOWLEDGEMENTS

Target RWE communities are collaborations among academic & community investigators, the pharmaceutical industry, patient community advocates. Target RWE communities are sponsored by TARGET PharmaSolutions Inc (d.b.a., Target RWE). We would like to thank all investigators, participants, and staff associated withTARGET-NASH. ClinicalTrials.gov Identifier: NCT02815891.

The authors acknowledge medical writing support by Dikshya Bastakoty, PhD.

## CONTACT INFORMATION

A. Sidney Barritt: sid\_barritt@med.unc.edu  
Arun Sanyal: arun.sanyal@vcuhealth.org