Poster Code: CO13

Healthcare Costs and Clinical Outcomes in Patients with Newly Diagnosed MASH or Suspected MASH with High FIB-4 Score in U.S. Adults

Tariku J. Beyene[1]; Chia-Chen Teng[1]; Mark Brunk-Grady[1]; Taylor Korth[1]; Eric Stanek[1]; Brendan Clark[2]; Bonnie M.K. Donato[2]; Meena B. Bansal[3]

[1] Carelon Research, Inc., Wilmington, DE, USA
[2] Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT, USA
[3] Division of Liver Diseases, Icahn School of Medicine at Mount Sinai, New York, NY, USA.

Introduction

- Metabolic dysfunction-associated steatohepatitis (MASH) prevalence is increasing, yet many individuals remain undiagnosed.
- MASH is associated with adverse health outcomes such as cirrhosis, liver failure, hepatocellular carcinoma, liver transplantation, and increased liver-related and all-cause mortality.[1]
- Recent clinical guidelines recommend non-invasive tests (e.g., Fibrosis-4 [FIB-4] score) to identify individuals at risk of advanced fibrosis.[2]
- Timely screening , diagnosis, and treatment are crucial to minimize the clinical and economic burden of MASH.

Objectives

The objective of this study was to characterize the economic and clinical outcomes burden in individuals with newly diagnosed MASH and suspected MASH based on FIB-4 score.

Methods

- A non-interventional cohort study utilized Healthcare Integrated Research Database (HIRD®) claims data to examine newly diagnosed and suspected MASH cohorts from January 2020-October 2024.
- Diagnosed MASH cohort had ≥1 inpatient or ≥2 outpatient claims with MASH diagnosis (ICD-10 K75.81), stratified by:
  - Baseline cirrhosis as: non-cirrhotic, compensated cirrhosis and decompensated cirrhosis
- Suspected MASH cohort included individuals with ad hoc calculated FIB-4 >2.67 based on available laboratory data, no MASH diagnosis, and at least 1 diagnosis of prediabetes, type 2 diabetes (T2DM), dyslipidemia, hypertension, or obesity.
- All were ≥18, with ≥12 months of continuous health plan enrolment prior to index date (the first MASH diagnosis or FIB-4>2.67 for suspected MASH); those with alcohol-related disorders or other liver diseases were excluded. Suspected MASH cohort further excluded individuals with baseline cirrhosis or a MASH diagnosis in the study period.
- Baseline characteristics included demographics and comorbidities.
- Clinical (hepatic, cardiovascular, and renal), mortality and cost outcomes were assessed over a variable follow-up period from index date to the earliest of death, health plan disenrollment, or study period end, using follow-up–adjusted denominators. Costs were reported per patient per year.
- Clinical outcomes and mortality were analyzed using Instant Health Data (IHD) (Panalgo, Boston, MA) and R 4.2.2.

Results

- We identified 20,069 individuals with diagnosed MASH (0.4% prevalence; mean age 54 years; 55% female; 5.8% with compensated and 7.5% decompensated cirrhosis at baseline, respectively) and 144,589 suspected MASH (3.8% prevalence; mean age 69 years; 49% female (**Table 1**)).
- Cardiometabolic comorbidity burden rose progressively with cirrhosis severity and was highest in decompensated cirrhosis (**Table 1**).
- Baseline all-cause annual total medical and pharmacy costs ranged $22,503 to $55,458 in diagnosed MASH and was $33,951 in suspected MASH (**Table 1, Figure 1**).

Results

TABLE 1. Characteristics During 12-Month Baseline Period

	Newly Diagnosed MASH, Stratified by Cirrhosis Status				Suspected MASH with FIB-4 >2.67
	N=20,069				N=144,589
	Non-Cirrhotic	Cirrhotic	Compensated Cirrhosis	Decompensated Cirrhosis*	
	N=17,391 (86.7%)	N=2,678 (13.3%)	N=1,174 (5.8%)	N=1,504 (7.5%)	
Age (years), Mean (SD)	52.3 (12.7)	62.2 (11.1)	60.3 (10.9)	63.7 (11.0)	68.8 (13.2)
Female, N (%)	9,437 (54.3%)	1,510 (56.4%)	693 (59.0%)	817 (54.3%)	71,359 (49.4%)
Race/Ethnicity, N (%)					
White	13,147 (75.6%)	2,358 (88.1%)	1,020 (86.9%)	1,338 (89.0%)	111,817 (77.3%)
Black	928 (5.3%)	65 (2.4%)	36 (3.1%)	29 (1.9%)	18,378 (12.7%)
Hispanic	2,215 (12.7%)	194 (7.2%)	84 (7.2%)	110 (7.3%)	7,784 (5.4%)
Comorbidity, N (%)					
T2DM	6,248 (35.9%)	1,887 (70.5%)	775 (66.0%)	1,112 (73.9%)	48,105 (33.3%)
Dyslipidemia	9,473 (54.5%)	1,667 (62.2%)	715 (60.9%)	952 (63.3%)	92,008 (63.6%)
Hypertension	10,058 (57.8%)	2,184 (81.6%)	904 (77.0%)	1,280 (85.1%)	107,940 (74.7%)
Obesity	7,430 (42.7%)	1,345 (50.2%)	571 (48.6%)	774 (51.5%)	31,391 (21.7%)
Annual Cost (2024 USD), Mean (SD)					
Inpatient	4,158 (28,435)	13,534 (36,182)	5,046 (20,672)	20,160 (43,565)	11,321 (49,018)
Emergency Department	1,206 (4,035)	2,015 (4,371)	1,306 (3,528)	2,568 (4,860)	939 (3,142)
Outpatient	10,105 (26,668)	17,652 (37,897)	13,061 (23,788)	21,235 (45,684)	13,361 (40,962)
Pharmacy	6,989 (19,908)	11,302 (21,593)	11,679 (23,572)	11,007 (19,916)	8,124 (29,086)
Total	22,503 (49,834)	44,802 (63,921)	31,150 (48,761)	55,458 (71,851)	33,951 (78,777)

TABLE 2. Cost And Clinical Complications During Follow-Up Period (Mean 1.7 Yrs)

	Newly Diagnosed MASH, Stratified by Baseline Cirrhosis Status				Suspected MASH with FIB-4 >2.67
	N=20,069				N=144,589
	Non-Cirrhotic	Cirrhotic	Compensated Cirrhosis	Decompensated Cirrhosis*	
	N=17,391 (86.7%)	N=2,678 (13.3%)	N=1,174 (5.8%)	N=1,504 (7.5%)	
Annual Cost (2024 USD), Mean (SD)					
Inpatient	21,239 (142,005)	74,722 (270,175)	36,020 (172,988)	104,932 (323,378)	24,639 (126,054)
Emergency Department	1,276 (5,158)	2,615 (8,705)	1,745 (5,345)	3,293 (10,565)	1,446 (4,963)
Outpatient	13,391 (37,790)	24,692 (48,494)	17,791 (35,569)	30,078 (55,992)	18,011 (52,974)
Pharmacy	9,450 (24,562)	15,639 (30,973)	15,849 (37,494)	15,476 (24,727)	10,121 (32,997)
Total	45,499 (156,434)	118,633 (281,192)	71,646 (184,574)	155,310 (333,425)	55,041 (150,969)
Clinical Complications Prevalence, N (%)					
Cirrhosis	1,872 (10.8%)	2678 (100.0%)	1,174 (100.0%)	1504 (100.0%)	4,547 (3.1%)
Decompensated cirrhosis	1,002 (5.8%)	1,807 (67.5%)	504 (42.9%)	1504 (100.0%)	3,283 (2.3%)
Liver failure	374 (2.2%)	646 (24.1%)	105 (8.9%)	541 (36.0%)	1,939 (1.3%)
Liver transplant	44 (0.3%)	120 (4.5%)	20 (1.7%)	100 (6.6%)	172 (0.1%)
HCC	99 (0.6%)	176 (6.6%)	55 (4.7%)	121 (8.0%)	517 (0.4%)
CVD**	4,224 (24.3%)	1,449 (54.1%)	514 (43.8%)	935 (62.2%)	77,383 (53.5%)
CKD (stage 3-5)	1,206 (6.9%)	692 (25.8%)	198 (16.9%)	494 (32.8%)	34,730 (24.0%)
Death/Mortality	341 (2.0%)	442 (16.5%)	72 (6.1%)	370 (24.6%)	17,912 (12.4%)

*Decompensated cirrhosis: Cirrhosis plus one or more diagnoses of decompensated cirrhosis, ascites, hepatic encephalopathy, varices, spontaneous bacterial peritonitis, hepatorenal syndrome, or hepatopulmonary syndrome. **CVD: cardiovascular disease, including myocardial infarction, coronary artery disease, peripheral arterial disease, heart failure, stroke, or atrial fibrillation/flutter; HCC: Hepatocellular carcinoma; CKD: chronic kidney disease; T2DM: Type 2 diabetes mellitus

Results

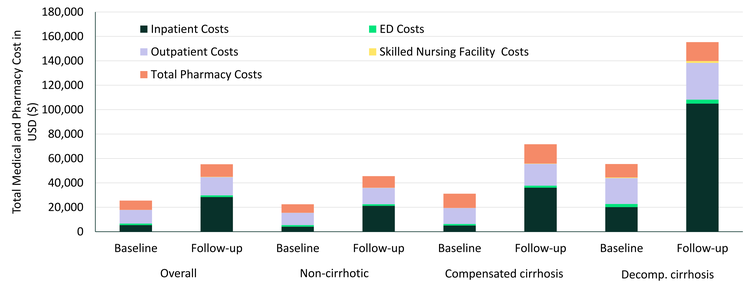

Figure 1. Annual healthcare costs of newly diagnosed MASH cohort stratified by baseline cirrhosis status

- Among individuals diagnosed MASH, all-cause healthcare cost burden increased progressively with cirrhosis severity.
- Mean annualized total costs including medical and pharmacy expenditures at follow-up were $45,499, $71,646, $155,310 and $55,041 in non-cirrhotic, compensated-cirrhosis, decompensated-cirrhosis and suspected MASH, respectively (**Table 2, Figure 1**).
- In the diagnosed MASH cohort, 10.8% of patients without baseline cirrhosis developed cirrhosis and 5.8% specifically developed decompensated cirrhosis over a mean 1.7-year follow-up period; in the suspected MASH cohort, 3.1% developed cirrhosis (**Table 2**).

Limitations

- MASH and cirrhosis status may be subject to misclassification, and suspected MASH may be underestimated, because cohort identification relied on claims data collected for administrative purposes, available FIB-4 results, and predefined algorithm criteria.

Conclusions

- Both diagnosed and suspected MASH individuals incur a significant clinical and economic burden, which in diagnosed MASH is further exacerbated by baseline presence/severity of cirrhosis.
- Over the follow-up period, healthcare costs increased 2.0-2.8-fold in newly-diagnosed and 1.6-fold in suspected MASH, driven by >2-fold higher inpatient utilization rates.
- The 9.5-fold higher prevalence of suspected MASH, and the added burden of cirrhosis at MASH diagnosis, highlights the potential value of screening lab data for FIB-4 scores to promote earlier MASH diagnosis and treatment.

References

1. Luthra R, Sheth A. Understanding MASH: An Examination of Progression and Clinical Outcomes by Disease Severity in the TARGET-NASH Database. *Adv Ther*. Feb 2025;42(2):1165-1195.
2. Rinella ME, Neuschwander-Tetri BA, Siddiqui MS, et al. AASLD Practice Guidance on the clinical assessment and management of nonalcoholic fatty liver disease. *Hepatology*. 2023;77(5):1797-1835.

Disclosures and Acknowledgements

This study was supported and funded by Boehringer Ingelheim Pharmaceuticals, Inc. The authors did not receive payment related to the development of the manuscript. The authors meet criteria for authorship as recommended by the ICMJE. Boehringer Ingelheim Pharmaceuticals, Inc. was given the opportunity to review the manuscript for medical and scientific accuracy as well as intellectual property considerations. Clark and Donato are employees of Boehringer Ingelheim Pharmaceuticals, Inc. Beyene; Teng; Brunk-Grady; Korth; Stanek are all associates of Carelon Research. Bansal has received Grant Support from NIH, CDC/NIOSH, Pfizer, The Kinetix Group, Petauri, Histoindex, Siemens and has served as a consultant for The Kinetix Group, Madrigal, Pfizer, Fibronostics, NOVO Nordisk, GSK, Boston Pharma, Merck, Boehringer-Ingelheim, CurveBio, mBIOTA, and Eli Lilly.

Boehringer Ingelheim

Health Economics and Outcomes Research

Poster presented at ISPOR 2026, May 17-20, 2026 | Philadelphia, PA | USA