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Total healthcare cost and characteristics associated with higher change in cost in patients with non-alcoholic steatohepatitis (NASH)

Zobair M Younossi[1]; Kamal Kant Mangla[2]; Abhishek Shankar Chandramouli[3]; Jeffrey V Lazarus[4]

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Plain Language Summary

Non-alcoholic steatohepatitis (NASH) is a type of fatty liver disease. NASH can lead to liver damage called cirrhosis.

We looked at health records to investigate the healthcare costs associated with NASH, and how cirrhosis and other conditions affect these costs.

People who develop NASH show an increase in total healthcare costs after diagnosis, which is also affected by how severe the NASH is and the presence of other conditions.

It may be possible to reduce healthcare costs with medication to treat NASH and associated conditions, and treatment should aim to stop the development of cirrhosis.

Aim

- One aim of the AWARE study was to determine the healthcare burden associated with NASH, focusing on change in cost post-NASH diagnosis and factors driving these healthcare costs using real world data from patients with NASH.

Introduction

- NASH is present in 1.5–6% of the general population and is significantly underdiagnosed.[1,2]
- The burden in NASH is due to multiple associated comorbidities, including liver-related complications, but also conditions such as cardiovascular disease (CVD).[2–4]
- As NASH progresses to cirrhosis, modeling data suggest an increase in burden of disease can be expected.[5]

Methods

- Data were collected from a large US healthcare dataset (electronic health records with linked claims) during the index period from October 1, 2015 to December 31, 2020.
  - Database is based on patients with body mass index ≥27 kg/m^2 at any point of time in the database, but not necessarily before NASH diagnosis.
- Adult patients diagnosed with NASH in the index period were included.
  - NASH diagnoses were identified using International Classification of Diseases (ICD) 10 Clinical Modification Coding.
  - Patients were required to have no evidence of hepatitis B/C, excessive alcohol use, liver transplantation prior to NASH diagnosis, pregnancy, or cancer based on ICD coding.
  - The non-cirrhotic patient population (NCP) and cirrhotic patient population (CP) were included; stratification by cirrhosis was based on evidence of cirrhosis (ICD9/ICD10) at baseline i.e., prior to NASH diagnosis.
- Baseline demographics and clinical characteristics were collected 12 months pre-index/at index and presented descriptively.
- Total annualized healthcare follow-up costs (United States dollars [$]) and change in total annualized healthcare costs after NASH diagnosis were reported as mean (SD) and median (interquartile range).
- Change in total healthcare cost was defined as: (annualized cost of patients post-NASH diagnosis) – (annualized cost of patients pre-NASH diagnosis).
- The effect on change in cost by baseline characteristics was assessed using a multivariate generalized linear model.

Results

- Of 4,989 patients diagnosed with NASH, 4,500 were included in the NCP and 489 were included in the CP (**Table 1**).
- Median (quartile [Q]1; 3) follow-up was 18 (8; 34) months for the NCP and 16 (7; 32) months for the CP.
- The CP had higher mean annualized costs than the NCP (**Table 2**).

Table 1: Baseline demographics and clinical characteristics*

	All patients	NCP	CP
N	**4,989**	**4,500**	**489**
Age, years	53.5 (11.2)	52.6 (11.2)	59.9 (9.3)
Female	56	55	62
Caucasian / other / unknown	73 / 8 / 19	73 / 8 / 19	76 / 6 / 18
NAFLD diagnosis			
In 1 year of baseline†	19.9	18.2	36.2
Clinical measures			
QCI	2.1 (1.7)	1.9 (1.5)	4.4 (1.9)
BMI, kg/m^2	35.0 (5.7)	35.0 (5.7)	35.1 (6.1)

*Data presented as mean (SD) or % unless otherwise specified; †NAFLD diagnosis in 1 year of baseline does not necessarily mean first NAFLD diagnosis for the patients.
BMI, body mass index; CP, cirrhotic patient population; NAFLD, non-alcoholic fatty liver disease; NCP, non-cirrhotic patient population; QCI, Quan-Charlson comorbidity index; SD, standard deviation.

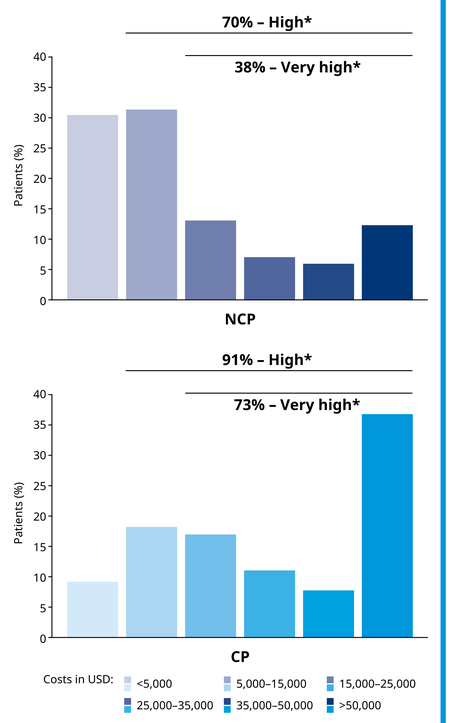
Table 2: Annualized follow-up costs (USD)

Follow-up cost (USD)	All patients	NCP	CP
N	**4,989**	**4,500**	**489**
Mean (SD)	34,183 (149,175)	28,707 (140,814)	84,582 (204,552)
Median (IQR)	11,185 (24,738)	10,085 (21,240)	30,317 (64,814)

CP, cirrhotic patient population; IQR, interquartile range; NCP, non-cirrhotic patient population; SD, standard deviation; USD, United States dollars.

Figure 1: Annualized follow-up total healthcare cost (USD) for patients with NASH

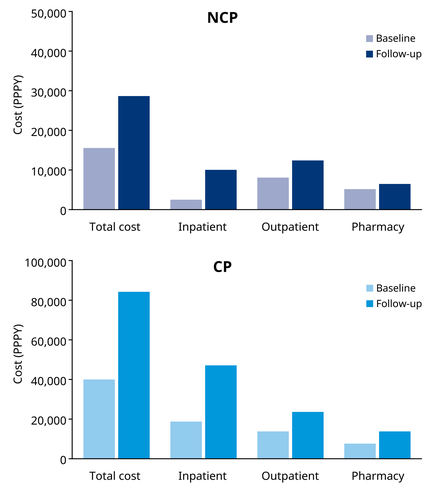
Key result



*High cost burden: >$5,000. Very high cost burden: >$15,000.
CP, cirrhotic patient population; NASH, non-alcoholic steatohepatitis; NCP, non-cirrhotic patient population; USD, United States dollar.

- The proportions of patients with a high cost burden (>$5,000) and a very high cost burden (>$15,000) are shown in **Figure 1**.
- In both the NCP and CP, an increase in total healthcare costs was observed post-NASH diagnosis, with the highest increase in costs during follow-up observed for inpatient costs (**Figure 2**).
- Baseline costs in the CP were already high (approximately $40,000), and increased approximately two-fold during follow-up.
- The mean increase in cost following diagnosis was higher in the CP than in the NCP (**Table 3**).

Figure 2: Increase in cost (USD) post-diagnosis



CP, cirrhotic patient population; NASH, non-alcoholic steatohepatitis; NCP, non-cirrhotic patient population; PPPY, per patient, per year; USD, United States dollars.

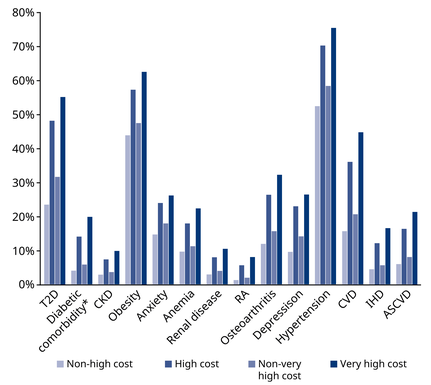
Table 3: Change in cost (USD) pre- vs. post-diagnosis

Change in cost (USD)	All patients	NCP	CP
N	**4,989**	**4,500**	**489**
Mean (SD)	16,270 (145,292)	13,202 (141,095)	44,509 (177,055)
Median (IQR)	2,534 (14,459)	2,267 (12,952)	10,370 (45,352)

CP, cirrhotic patient population; IQR, interquartile range; NCP, non-cirrhotic patient population; SD, standard deviation; USD, United States dollars.

- Female patients had higher costs as compared to male patients.
- For the NCP, higher percentage increases in costs were associated with baseline characteristics (presence vs. absence) and disease severity:
  - Depression (57%), osteoarthritis (51%), anemia (44%), CVD (71%); others: anxiety (19%) and hypertension (19%).
  - Adaptive Diabetes Complexity Severity Index (36% per unit increase), Quan-Charlson Index (21% per unit increase), anti-diabetes medication (12% per additional medication class), and increasing use of CVD drug classes (8% per additional medication class).
- In the NCP, patients in the high and very high cost groups (vs. non-high cost group) had higher rates of all comorbidities, especially type 2 diabetes and CVD (**Figure 3**).

Figure 3: Rates of baseline comorbidities in the NCP by cost (USD) in follow-up



*Diabetic retinopathy, diabetic neuropathy, and diabetic nephropathy.
ASCVD, atherosclerotic cardiovascular disease; CKD, chronic kidney disease; CVD, cardiovascular disease; IHD, ischemic heart disease; T2D, type 2 diabetes; RA, rheumatoid arthritis; USD, United States dollars.

Conclusions

- There is a significant proportion (~70%) of the non-cirrhotic patient population who have a large cost burden that may be reduced by pharmacotherapy for treatment of NASH and associated comorbidities.
- Due to the very high cost burden in the cirrhotic patient population, the aim of disease management should be to stop progression to cirrhosis and associated complications.

[1]Center for Liver Disease, Inova Medicine, Falls Church, VA, United States; [2]NovoNordisk A/S, Søborg, Denmark; [3]NovoNordisk Service Center India Pvt Ltd, Bangalore, India; [4]Barcelona Institute for Global Health (ISGlobal), Hospital Clinic, University of Barcelona, Barcelona, Spain.

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