SAT-251

Health Care Costs are Double for Nonalcoholic Fatty Liver Disease (NAFLD)/Nonalcoholic Steatohepatitis (NASH) Patients with Compensated Cirrhosis (CC) who Progress to End-Stage Liver Disease (ESLD)

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BACKGROUND

- Nonalcoholic fatty liver disease/nonalcoholic steatohepatitis (NAFLD/NASH) is one of the most common causes of cirrhosis in the United States.[1]
- Compensated cirrhosis (CC) patients often develop complications and advance to end stage liver disease (ESLD) which includes decompensated cirrhosis (DCC), hepatocellular carcinoma (HCC) and liver transplant (LT) which may lead to death.

AIM

- The study objective was to characterize the long-term economic burden of NAFLD/NASH CC patients stratified by those who remain at CC vs. whose who progress from CC to ESLD.

METHODS

- **Design:** This was a retrospective, observational cohort study (see Figure 1).
- **Data Source:** 20% sample US Medicare from 2007-2015 (including Part A, Part B, and Part D).
- **Study population:** NASH/NAFLD diagnosed patients (patients with ≥ 1 claim of ICD-9-CM [571.8, 571.9] or ICD-10 [K76.0, K75.81] diagnosis codes for NAFLD/NASH) with CC aged ≥18 years who have Medicare fee-for-service (FFS) coverage.
- **Exclusion criteria:** Patients with other defined causes of liver disease were excluded (alcoholism, alcoholic liver disease, viral hepatitis, mumps hepatitis, HIV, Wilson's disease, autoimmune hepatitis, chronic toxic hepatitis, Gaucher, lysosomal acid lipase deficiency, primary biliary cholangitis, hemochromatosis and primary sclerosing cholangitis).
- **Index date:** The first CC claim date was the CC index date.
  - ICD-9 diagnosis code 571.5 (cirrhosis of liver without mention of alcohol).
  - ICD-10 diagnosis codes (K74.6, K74.60, and K74.69 unspecified or other cirrhosis of liver).
- **Outcomes:**
  - Demographics and comorbidities by progression status.
  - Healthcare costs estimated during 2 year pre-index and 1 year pre-index along with 1 year, 2 years, 3 years, 4 years, and 5 years of follow-up post-index (first CC diagnosis index date).
  - Total 7-year cumulative costs were calculated per patient (PP) annually and adjusted for 2015 USD.
  - Patients were evaluated according to three groups: (1) all CC patients, (2) patients with no progression beyond CC, and (3) patients who progressed from CC to ESLD anytime during the study period.
- **Follow-up:**
  - From CC index date to the earliest of death, end of Medicare coverage, December 31, 2015, or 5 years after index date; minimum 1 month follow-up required.

RESULTS

Table 1. Patient Selection Flowchart

Patient Selection Process	No. of patients
20% sample of Medicare patients with coverage between 2008-2015	10,826,456
Patients who had NAFLD/NASH diagnosis code between 1/1/2008 and 11/30/2015	621,253
Patients without any excluding diseases between 2007-2015	393,796
Patients who were defined with CC between 2007-2015	12,200
Patients have at least 1 month follow-up after CC index date	10,584
Patients with incident CC* and Medicare coverage at least 6 months pre-CC index date	**3,775**

- 6% percent of the Medicare patients in this study had NAFLD/NASH.
- 3% of the NAFLD/NASH patients in this study had CC.

Figure 1. Study Period and Outcomes

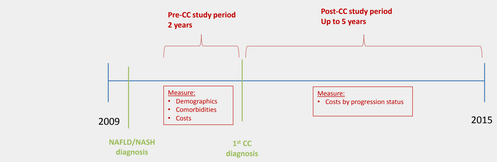
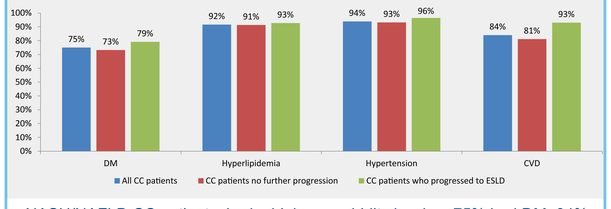


Table 2. NAFLD/NASH CC Patient Demographics

	All CC	CC with no further progression	CC with progression to ELSD
Patients N, %	3,775	2,727 (72%)	1,048 (28%)
Female, %	63%	63%	65%
Age mean, (SD)	66.95 (10.90)	66.55 (10.90)	68.01 (10.70)
Age group, %			
18-64	30%	31%	28%
65-69	29%	30%	28%
70-74	20%	20%	20%
75-79	12%	11%	13%
80+	9%	8%	11%
Race, %			
White	87%	87%	88%
Black	5%	5%	4%
Other	8%	9%	8%

- Medicare NAFLD/NASH CC patients had a mean age of 67, a higher female proportion (63%), were primarily white (87%).
- 28% of CC patients progressed to ESLD over the study period. Characteristics of age, gender, and race were similar between patients who did and did not progress to ESLD.

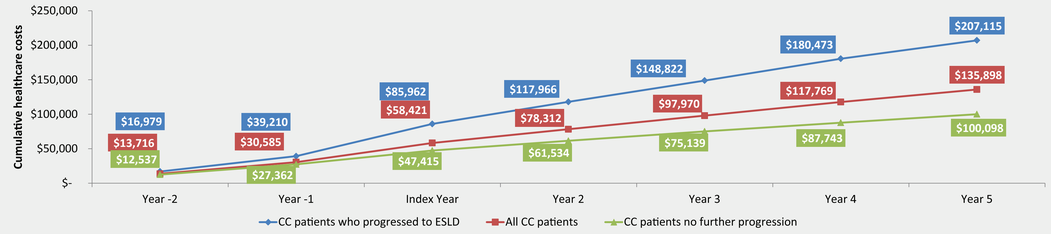
Figure 2. NAFLD/NASH CC Patient Comorbidities



- NASH/NAFLD CC patients had a high comorbidity burden: 75% had DM, 84% had CVD, 92% had hyperlipidemia, and 94% had hypertension.
- The comorbidity burden was generally similar in CC patients who progressed to ESLD compared to CC patients who did not progress further.

RESULTS (cont'd)

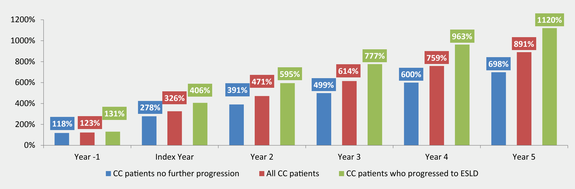
Figure 3. NAFLD/NASH CC Patients Cumulative Mean Total Healthcare Costs



P<0.0001 in each year between CC patients who progressed to ESLD and CC patients no further progression
N for all cirrhosis patients group was: Year -2 = 2,814; Year -1 = 3,501; Index year = 3,775; Year 2 = 2,682; Year 3 = 1,850; Year 4 = 1,279; Year 5 = 837

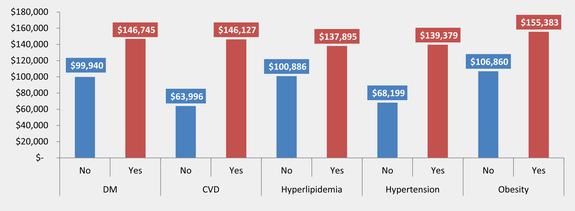
- In the time period from 2 years prior to CC diagnosis to 5 years following, the overall CC patients group experienced substantial cumulative healthcare costs of over $135,000 (891% increase in cumulative healthcare costs).
- NAFLD/NASH CC patients who progress to ESLD had significantly higher cumulative healthcare costs of $207,115 compared to CC patients who did not progress further who had cumulative healthcare costs of $100,098 (P<0.0001).

Figure 4. NAFLD/NASH CC Patients Cumulative Percent Increase in Costs



- The overall CC patient group experienced an overall 891% increase in cumulative costs over 7 years.
- CC patients who progress to ESLD had a 1120% increase in cumulative in costs, which was higher than the 698% increase for patients who did not progress beyond CC.

Figure 5. NAFLD/NASH CC Patients 7 Year Cumulative Healthcare Costs by Comorbidities



- NAFLD/NASH CC patients with additional comorbidities had substantially higher cumulative healthcare costs over 7 years: Costs were 47% higher for DM patients, 128% higher for CVD patients, and 104% higher for hypertension patients compared to patients without these comorbidities.

CONCLUSIONS

- This study of NAFLD/NASH patients with CC patients has shown:
  - Over the 7 year study period, 28% of CC patients progressed to ESLD.
  - The overall cohort of NAFLD/NASH CC patients experienced substantial cumulative increase in healthcare costs of over $135,000 (891% increase).
  - Cumulative healthcare costs for CC patients who progressed to ESLD were more than double than for patients who did not progress beyond CC ($207,115 vs. $100,098; P<0.0001).
  - This study underscores the significant economic burden of NAFLD/NASH cirrhosis patients and new treatment options are urgently needed to prevent progression NAFLD/NASH patients to advanced liver disease.

LIMITATIONS

- Results are limited to the US Medicare population with cirrhosis.
- Results are not adjusted for controlled variables.
- As with any claims databases, these data were subject to data coding limitations, data entry error, and misclassification of NAFLD/NASH.

REFERENCES

1. Luis Calzadilla Bertot and Leon Anton Adams. The Natural Course of Non-Alcoholic Fatty Liver Disease. Int J Mol Sci 2016 May 17(5):774

DISCLOSURES

- Study funded by Gilead Sciences, Inc