USING REAL WORLD DATA TO EXAMINE DIRECT ACTING ANTIVIRAL USE AMONG HEPATITIS C PATIENTS DEFINED BY FIBROSIS SCORE AND HEPATITIS C VIRAL LOAD

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OBJECTIVES

The aims of this study were to use real world data to:

1) Describe treatments among hepatitis C (HCV) patients stratified by fibrosis score (FS)[1] and HCV viral load (HVL).
2) To assess virologic response between DAA-treated versus untreated patients and among DAA-treated patients with high versus low HVL.

METHODS

HCV patients were identified through TriNetX, an electronic medical record network (Figure 1). The first recorded FS after an HCV diagnosis defined the index event (IE). Patients were stratified by FS: F0-F2, F3-F4 without cirrhosis, and F4 with cirrhosis[1]. Within each FS strata, patients were grouped by HVL, measured in the month before the IE: high HVL (800,000+ IU/mL), low HVL (615-799,999 IU/mL) and unidentifiable/unknown (UI/UK) HVL (<615 IU/mL).

Direct acting antiviral (DAA) treatment 12 months following the IE was examined. Any treatments recorded on the same day were combined into a single line. If a new DAA was recorded after the first line, a second line of treatment was initiated.

The likelihood of achieving an undetectable viral load between DAA-treated versus untreated patients, and DAA-treated patients with high vs. low viral loads, was assessed during the 12-24 months following the IE. Models were adjusted using a 1:1 matched propensity score model.

All patient characteristics were defined with ICD9/10, RxNorm, or LOINC codes.

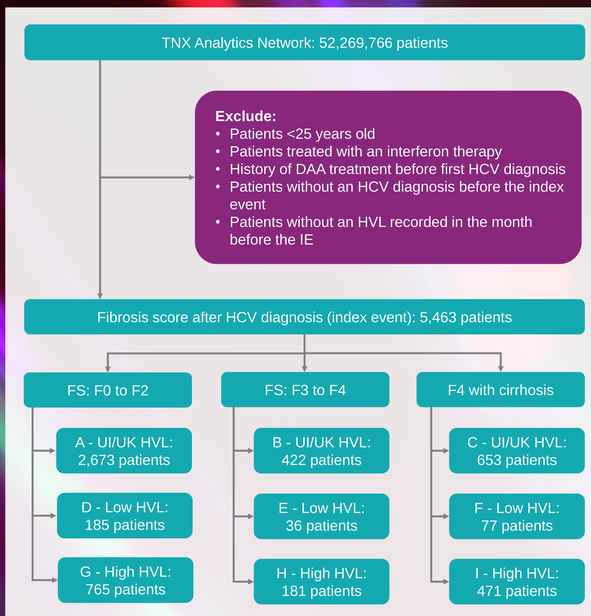

Figure 1. Patient flow diagram

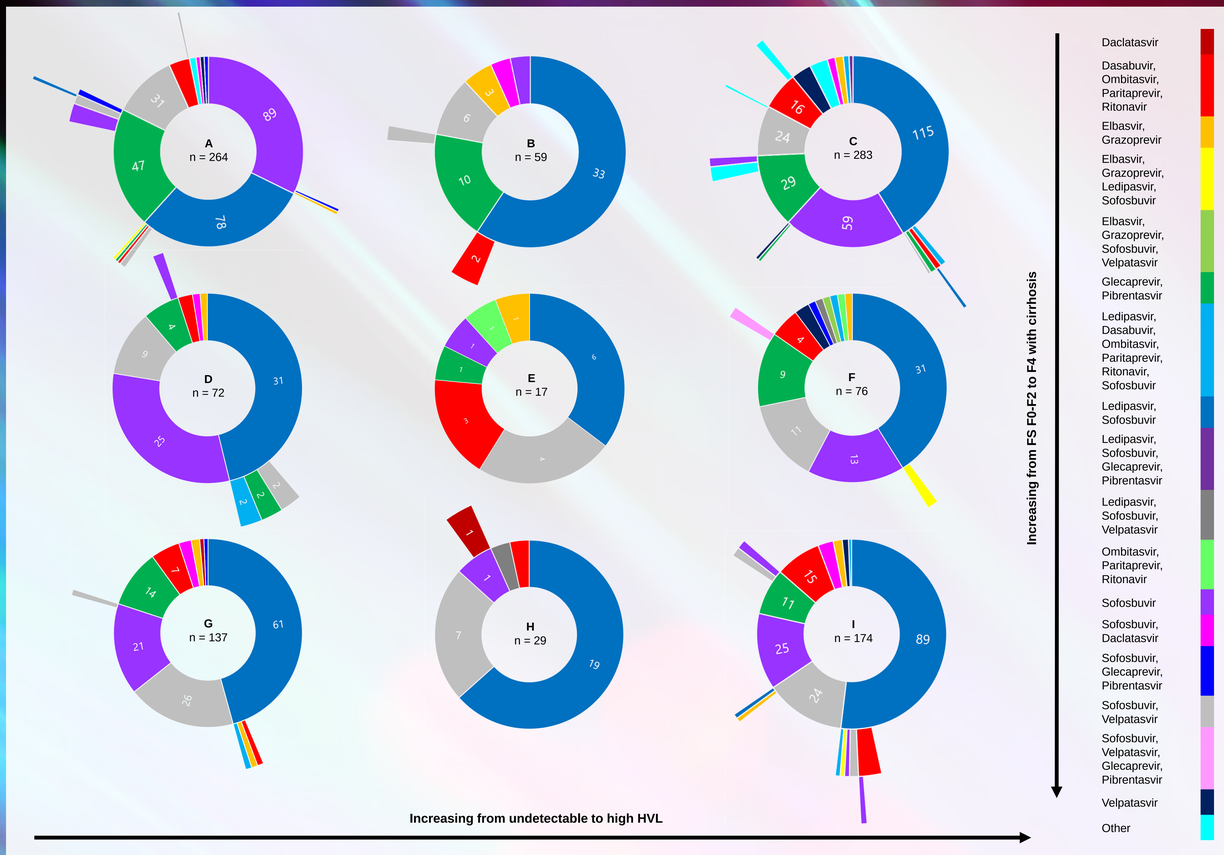

Figure 2. First, second, and third line DAA treatment by FS and HVL

Note: Numbers within segments of the sunburst plot refer to patient counts for that segment.
Row 1: **A** (F0-F2 with undetectable/unknown HVL, 90% untreated); **B** (F0-F2 with low HVL, 68% untreated); **C** (F0-F2 with high HVL, 63% untreated).
Row 2: **D** (F3-F4 with undetectable HVL, 83% untreated); **E** (F3-F4 with low HVL, 53% untreated); **F** (F3-F4 with high HVL, 58% untreated).
Row 3: **G** (F4 with cirrhosis and undetectable HVL, 79% untreated); **H** (F4 with cirrhosis and low HVL, 63% untreated); **I** (F4 with cirrhosis and high HVL 63% untreated).

RESULTS

DAA-treated patients had a mean age of 57 (10.2) at the time of the IE (Table 1). Most patients were untreated (79%). Of those that did receive treatment, most received a single line of DAA therapy in the 12 months after the IE. The most common DAAs in line one, were Ledipasvir and Sofosbuvir followed by Sofosbuvir alone. Second- and third-line treatments varied across FS and HVL defined populations. Diversity in DAA ingredients was greater among patients with a high HVL, irrespective of FS.

After adjusting for baseline confounders (Table 1), patients treated with a DAA were 2.3 (1.8-3.0) times as likely to achieve a positive virologic response in the 12-24 months following treatment. There was no difference between DAA-treated patients with a high versus low viral load.

Table 1. Patient characteristics

Note: all standardized mean differences <10% after matching. Baseline confounders included demographics, liver disease, mental and behavioral disorders, and other communicable diseases.

		Before matching		After matching	
		DAA-treated	Untreated	DAA-treated	Untreated
Total (N)		1,147	4,316	781	781
Mean age at index (SD)		57.0 (10.2)	52.0 (12.6)	57.0 (10.2)	57.0 (9.7)
Male (%)		62.1	58.0	62.2	62.9
White (%)		55.6	68.0	55.7	54.9
Fibrosis score	0-0.58 (%)	45.4	60.5	45.5	45.7
	0.58-0.75 (%)	18.0	14.0	18.1	19.2
	0.74-1 (%)	35.9	26.4	35.9	35.5

CONCLUSIONS

DAA treatment differed by FS and HVL. Patients with a higher HVL were more likely to be treated with a DAA. These patients also switched DAA treatment more frequently than patients in other populations (groups C, F, and I). The exception to this was the subset of patients with the lowest HVL and FS (group A). Although virologic response did not differ between DAA-treated patients with a high versus low HVL, DAA treatment improved virologic response overall when compared to untreated patients. While most patients in the analysis did not receive DAA treatment, this finding aligns with other published findings. The WHO reports that only 13% of patients worldwide receive curative treatment[2], representing a substantial unmet need for treatment in this vulnerable patient population.

1. Bedossa P, Poynard T, The French METAVIR Cooperative Study Group. An algorithm for grading activity in chronic hepatitis C. Hepatology 1996;24:289–293.
2. WHO. Hepatitis C. https://www.who.int/news-room/fact-sheets/detail/hepatitis-c

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