

## BACKGROUND

- About 2.4 million people are living with hepatitis C virus (HCV), about 1% of adults in US
- Direct-acting antiviral drugs (DAAs) of HCV achieve high success with excellent safety profile
- Elevated alanine aminotransferase (ALT) shown to correlate with hepatocellular damage and fibrosis
- We evaluated the ability of serum ALT level at SVR12 (undetectable HCV viral load after 12 weeks of therapy) to predict treatment outcome

## METHODS

- Large retrospective study:
  - Collected baseline demographics, treatment characteristics, and outcomes of DAA-treated patients treated between:
    - January 2015 through January 2019 (VAMHCS)
    - May 2015 through November 2015 in federally qualified health centers in Washington, DC (ASCEND study)
- With VAMHCS (confirmatory set) and ASCEND study (training set), receiver operator curves generated to determine the predictive value of ALT at SVR12 for treatment outcome
- Key Exclusion Criteria – excluded from analysis:
  - Missing treatment outcomes
  - Outcomes outside of SVR or relapse
  - Missing post-treatment ALT within 90 days following SVR12 timepoint
  - Did not complete treatment

Table 2. Mean ALT values at SVR and relapse

	ALT SVR12	ALT Relapse
VAMHCS	21.19 (SD 13.98)	57.84 (SD 41.06)
ASCEND	17.89 (SD 11.62)	42.53 (SD 19.61)
Combined	20.25 (SD 13.43)	53.11 (SD 36.33)

Table 1: Characteristics of Subjects Completing Hepatitis C Treatment

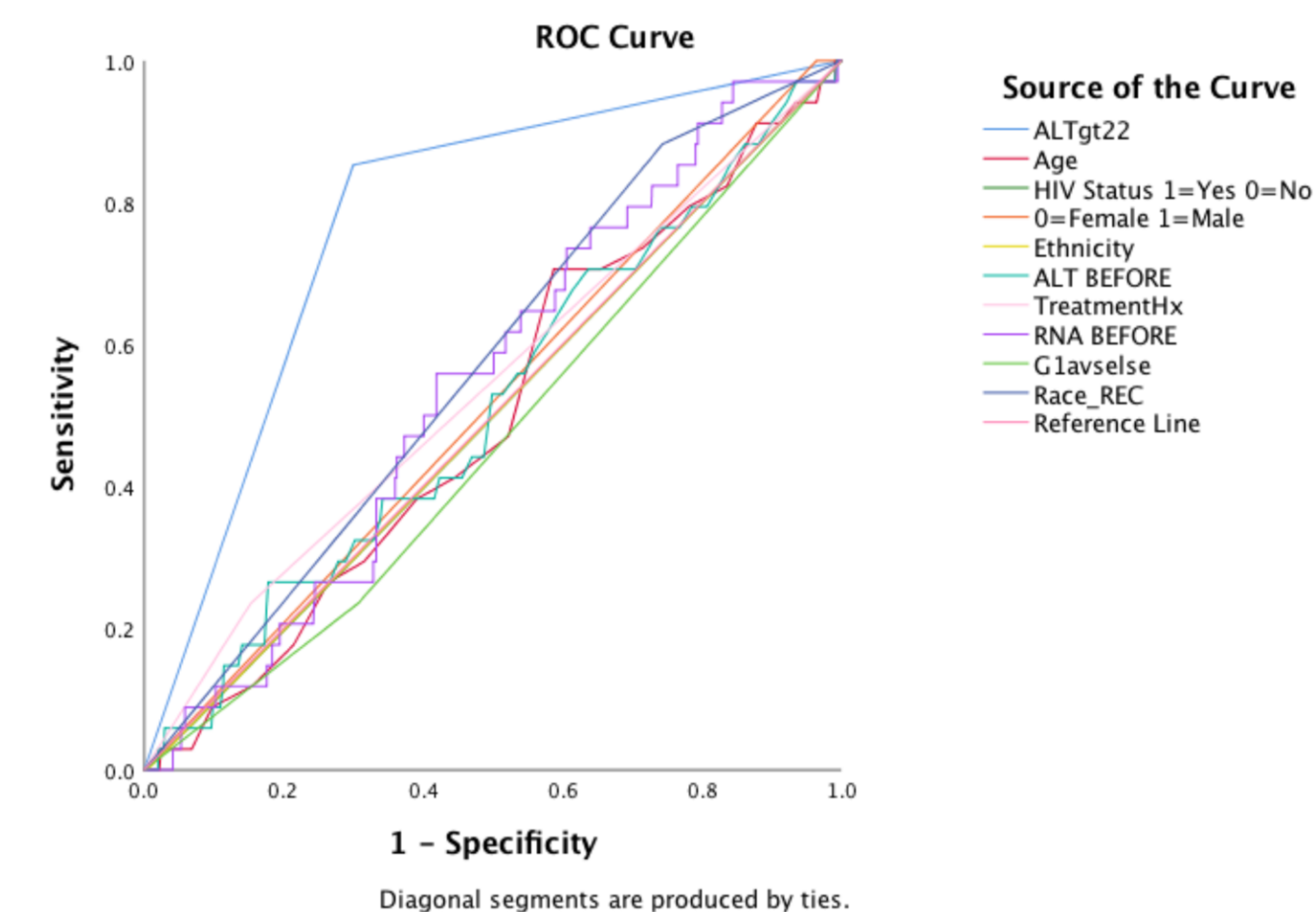
	ASCEND n=405 (%)	VAMHCS n=1010 (%)	$\chi^2$
Male	286 (68.1)	977 (96.7)	<.001 (232.9)
Race/Ethnicity			
White	13 (3.2)	242 (24.0)	<.001 (101.93)
Black	385 (95.1)	750 (74.3)	
Other	7 (1.7)	8 (.8)	
Missing		8 (.8)	
Hispanic	7 (1.7)	4 (.4)	.011 (6.54)
Fibrosis Score*			<.001 (1415.0)
Not available		81 (8.0)	
0-1	108 (26.7)	334 (33.1)	
2	146 (36.0)	220 (21.8)	
3	65 (16.0)	128 (12.7)	
4	86 (21.2)	247 (24.5)	
Genotype			<.001 (28.04)
1a	296 (73.1)	677 (67.0)	
1b	109 (26.9)	235 (23.3)	
2		48 (4.8)	
3		13 (1.3)	
4		3 (.3)	
Missing		34 (3.4)	
HIV Positive	81 (20)	63 (6.2)	<.001 (59.9)
Treatment Experienced	70 (17.3)	158 (15.7)	.453 (.564)
SVR12	388 (95.8)	972 (96.2)	.702 (.147)
	M (SD)	M (SD)	
Age	59.04 (6.773)	64.72 (6.724)	.640 (F, 218)
Baseline HCV RNA (log)	6.288 (.569)	5.974 (.802)	<.001 (F, 14.577)
Baseline ALT	48.81 (33.44)	52.78 (36.90)	.283 (F, 1.152)

\*Liver fibrosis staging within the ASCEND study was documented as Metavir staging from any liver biopsy or serologic biomarker test within 3 years of the screening visit. VAMHCS population scoring was based on Metavir cutoff and fibrosis scores from transient elastography.

## RESULTS

- 1415 patients included: 1010 from VA, 405 ASCEND
- Baseline characteristics of analyzed patients are shown in Table 1
- 96% (n=1360) achieved SVR12, <4% (n=55) relapsed
- Mean ALT at SVR12 was lower than ALT in relapsed patients (Table 2)
- ALT >22 predicted an increased risk of relapse

Figure 1. ROC Analysis



## CONCLUSIONS

- ALT greater than 22 at SVR12 corresponded with an increased risk of relapse and was independent of variables previously associated with relapse (HIV coinfection, sex, treatment history, fibrosis staging).
- Limiting HCV viral load testing to patients with ALT >22 at SVR may reduce overall burden of HCV treatment costs for the majority of HCV treated patients.

## REFERENCES

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