

Hepatitis C Virus Sustained Virologic Response Rates in African Americans

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BACKGROUND

- African Americans comprise 11% of the United States (US) population but approximately 25% of US hepatitis C virus (HCV) infections¹⁻²
- Historic HCV treatment with interferon and ribavirin was associated with lower sustained virologic response (SVR) rates in African American patients partly due to increased prevalence of non CC IL28B genotypes³⁻⁴
- Specific HCV recommendations for African Americans exist in both the AASLD/IDSA HCV guidance and package labeling for one regimen⁵⁻⁶

OBJECTIVE

- To compare SVR rates for African American (AA) and non-African American (non-AA) patients in a multi center cohort

METHODS

Sub-analysis of a previously described multi center, retrospective cohort⁷

Study Population:

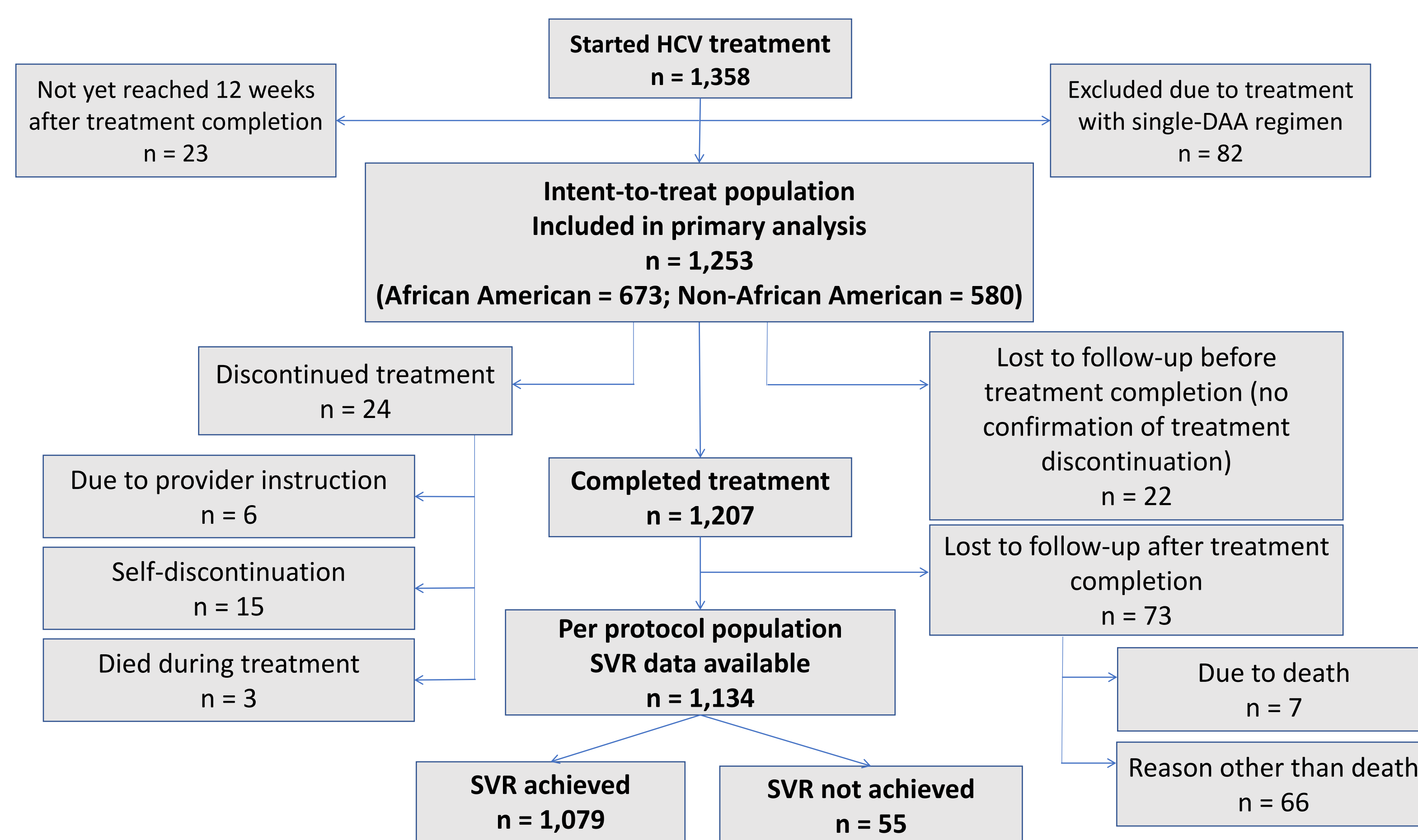
- Initiated HCV treatment with a dual or triple direct-acting antiviral (DAA) regimen between January 1, 2014 and March 12, 2018
- Excluded if 12 week SVR was not measured by September 7, 2018

Statistical analysis:

- Intent-to-treat and per protocol analyses were used for the primary endpoint
- Descriptive statistics were provided to define the overall study population
- χ^2 tests (p values <0.05 regarded as statistically significant) were used to identify significant associations between SVR rates and drug-drug interactions (DDIs), adverse drug reactions (ADRs), or adherence

RESULTS

Figure 1. Overall Patient Attrition



RESULTS

Table 1. Baseline Patient Characteristics (N = 1,253)

Characteristic	African American n = 673	Non-African American ^a n = 580	p	
Age (years), mean (SD)	60.5 (7.5)	53.8 (11.4)	<.01	
BMI, mean (SD)	29.0 (6.5)	28.3 (5.9)	0.06	
Born between 1945-1965, n (%)	576 (85.6)	352 (60.7)	<.01	
Male, n (%)	417 (62.0)	384 (66.2)	0.12	
Insurance, n (%)	Medicaid/Medicaid Managed Care	253 (37.6)	202 (34.8)	<.01
	Medicare Part D	232 (34.5)	142 (24.5)	
	Private Insurance	156 (23.2)	174 (30.0)	
	No Insurance/Unknown/Other	32 (4.8)	62 (10.7)	
HIV coinfection, n (%)	118 (17.5)	107 (18.4)	0.67	
History of solid organ transplantation, n (%)	41 (6.1)	49 (8.4)	0.11	
Diabetes, n (%)	190 (28.2)	113 (19.5)	<.01	
Psychiatric illness, n (%)	196 (29.1)	224 (38.6)	<.01	
HCC, n (%)	20 (3.0)	29 (5.0)	0.06	
Treatment-naïve, n (%)	555 (82.5)	467 (80.5)	0.37	
Genotype, n (%)	1a	418 (62.1)	361 (62.2)	<.01
	1b	216 (32.1)	83 (14.3)	
	Other	39 (5.8)	136 (23.4)	
Cirrhotic, n (%)	266 (39.5)	239 (41.2)	0.54	
CTP class, n (%) ^b	A	227 (33.7)	191 (32.9)	0.27
	B	31 (4.6)	38 (6.6)	
	C	8 (1.2)	10 (55.9)	
DAA Regimen	Sofosbuvir/Ledipasvir ± Ribavirin (RBV)	433 (64.3)	324 (16.9)	<.01
	Elbasvir/Grazoprevir ± RBV	84 (12.5)	30 (7.8)	
	Sofosbuvir + Simeprevir ± RBV	66 (9.8)	45 (7.8)	
	Glecaprevir/Pibrentasvir	40 (5.9)	39 (6.7)	
	Sofosbuvir/Velpatasvir ± RBV	33 (4.9)	98 (5.2)	
	Other	17 (2.5)	44 (7.6)	
Recent alcohol use, n (%) ^c	197 (29.3)	193 (33.3)	0.10	
Recent IVDU, n (%) ^c	26 (3.9)	44 (7.6)	<.01	
Recent use of non-IVDU illicit substances, n (%) ^c	100 (14.9)	99 (17.1)	0.22	

BMI: body mass index; DAA: Direct Acting Antiviral; HIV: human immunodeficiency virus; HCC: hepatocellular carcinoma; CTP: Child-Turcotte-Pugh; IVDU: intravenous drug use; ^aWhite: 389 (30.9%), Hispanic: 12.5%, Other: 36 (2.8%); ^bCTP score calculated in those with cirrhosis; ^cRecent use defined as use in the previous 6-12 months

Figure 2. Sustained Virologic Response (SVR) by Race

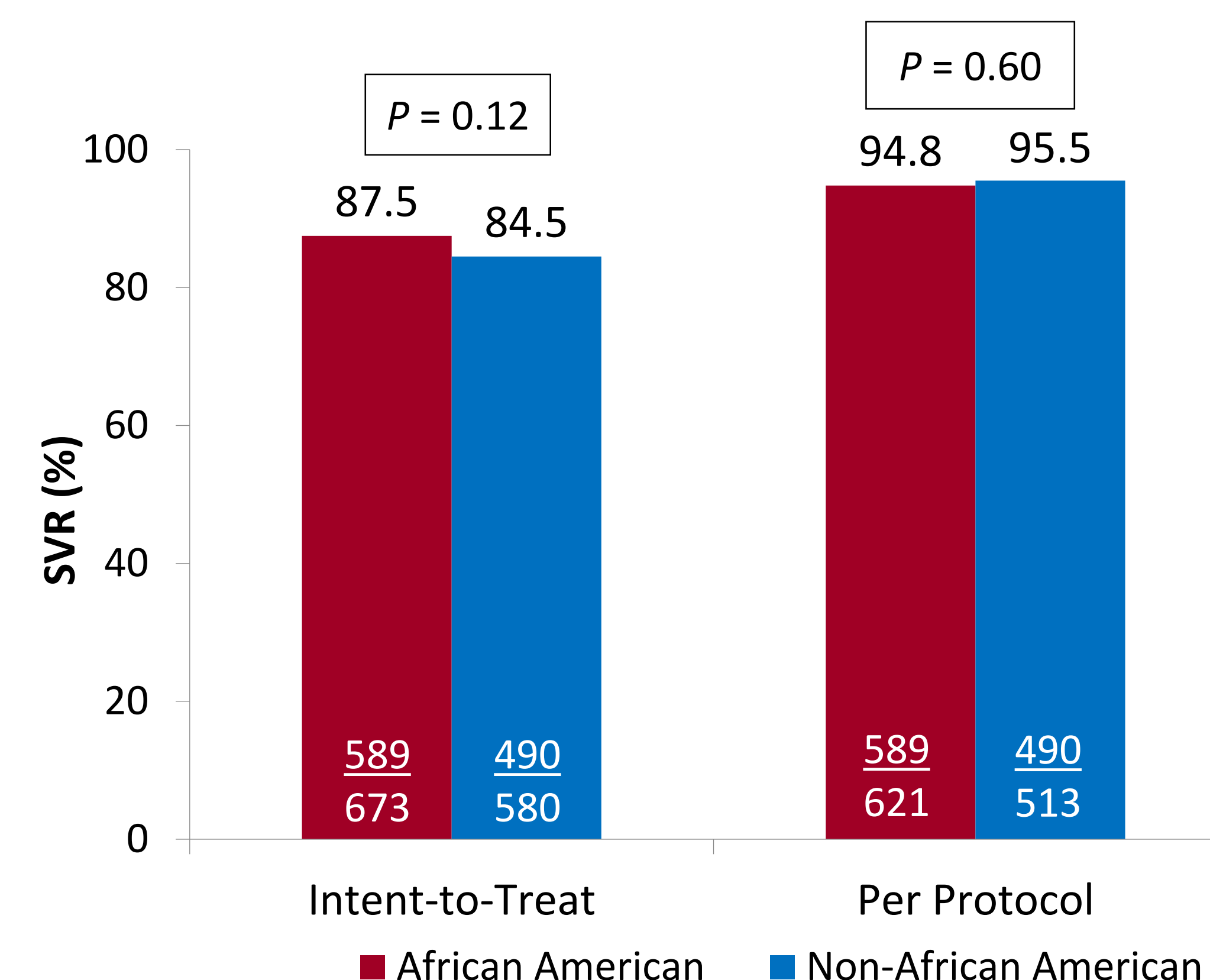
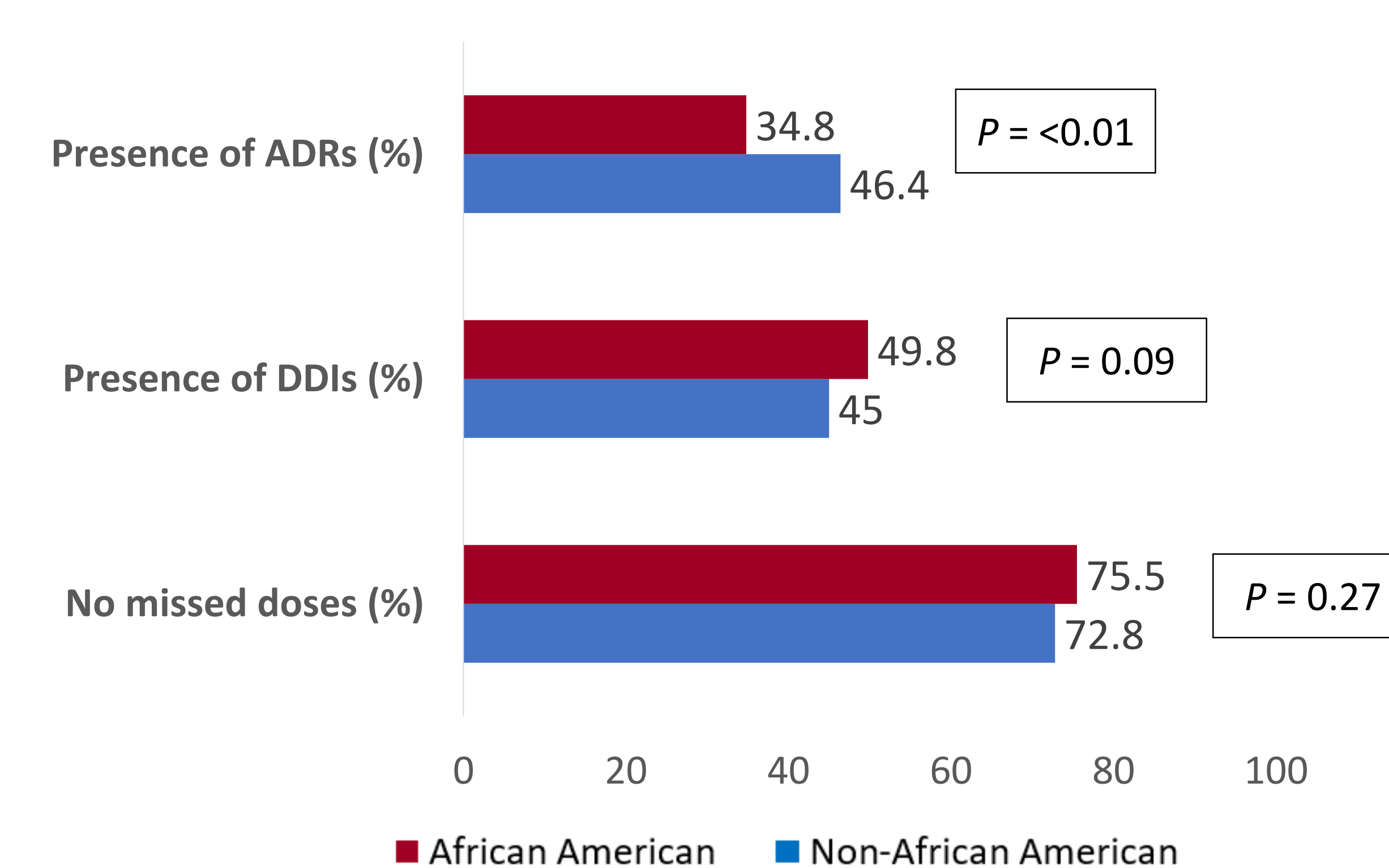


Figure 3. Adherence, Baseline Drug-Drug Interactions (DDIs), and Adverse Drug Reactions (ADRs) by Race



CONCLUSIONS

- Our study demonstrated no statistically significant difference in SVR rates between AA and non-AA patients treated with HCV DAAs
- Non-AA patients reported a statistically significant higher rate of ADRs than the AA patient population
- The differences in baseline demographics seen in our population include: age, insurance, diabetes, psychiatric illness, genotype, DAA regimen, and recent IVDU

LIMITATIONS

- This study was a sub-analysis from a previously described multi center retrospective cohort involving four academic medical centers
- We did not stratify SVR rates between specific medication regimens by race-groupings, which remains a topic for future study

REFERENCES

- Denniston MM et al. Chronic Hepatitis C Virus Infection in the United States, National Health and Nutrition Examination Survey 2003 to 2010. *Ann Intern Med.* 2014;160:293-300
- Armstrong GL et al. The prevalence of hepatitis C virus infection in the United States, 1999 through 2002. *Ann Intern Med.* 2006;144:705-714
- Rajender Reddy K et al. Racial differences in Response to Therapy with Interferon in Chronic Hepatitis C. *Hepatology.* 1999;30(3):787-793
- Ge D et al. Genetic variation in IL28B predicts hepatitis C treatment-induced viral clearance. *Nature.* 2009;461(7262):399-401
- Wilder JM et al. Safety and efficacy of ledipasvir-sofosbuvir in black patients with hepatitis C virus infection: a retrospective analysis of phase 3 data. *Hepatology.* 2016;63:437-444
- AASLD-IDSA. Treatment-Naïve Genotype 1a Without Cirrhosis. <http://www.hcvguidelines.org/treatment-naive/gt1a/no-cirrhosis>. [October 15, 2019]
- Koren DE et al. Expanding Hepatitis C Care and Cure: National Experience Using a Clinical Pharmacist-Driven Model. *OFID.* 2019;6(7):ofz316

DISCLOSURES

Investigators received an investigator sponsored research grant from Gilead Sciences Inc. The poster contents are solely the responsibility of the authors and do not necessarily represent the official views of Gilead. Drs. Koren, Martin, and Teply have served on advisory board(s) for Gilead. Dr. Teply has served on advisory boards for AbbVie and serves on the speaker's bureau for Gilead Sciences and AbbVie. Dr. Martin has served on an advisory board for AbbVie, has received grant funding from Merck, and is a minor shareholder of AbbVie, Gilead, and Merck.



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