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Racial and Ethnic Disparities Among Participants in Hepatocellular Carcinoma Clinical Studies Evaluating Transarterial Therapies

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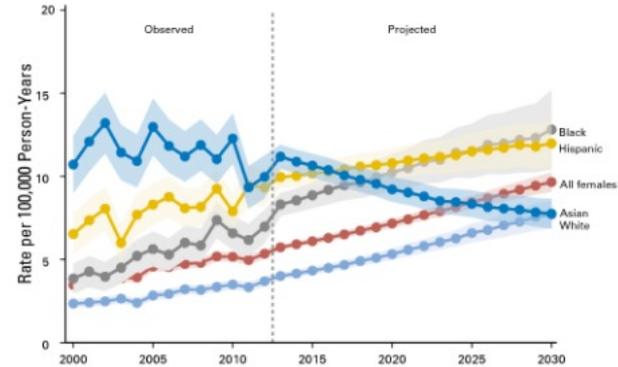
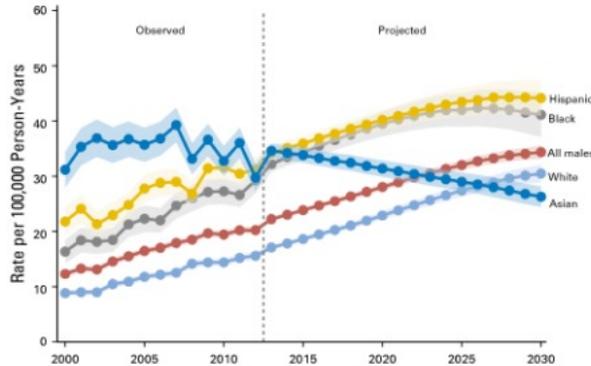
Introduction

- Image-guided therapies play an important role in the management of patients with hepatic tumors.
- There are various transarterial therapies available for managing hepatic tumors, including bland embolization, chemoembolization, radioembolization, and hepatic artery.



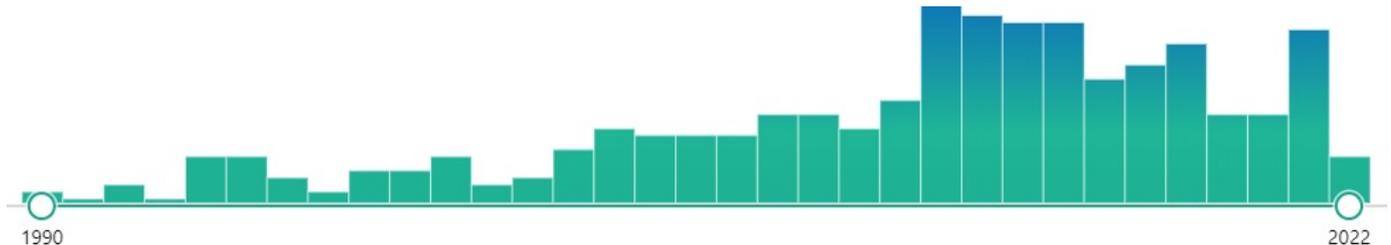
Introduction

- Incidence and mortality of HCC in the United States is rising
- Minorities like African Americans and Hispanic individuals have an disproportionately high risk compared to other races and ethnicities



Introduction

- Literature has shown underutilization of curative HCC treatments and differential response in different racial and ethnic sub-groups
- Enrollment of diverse patient populations in cancer clinical trials has shown to be lagging– leads to lack of generalizability
- Now new clinical trials are evaluating the use of transarterial therapies for HCC management



Total number of trials reported on PubMed= 302

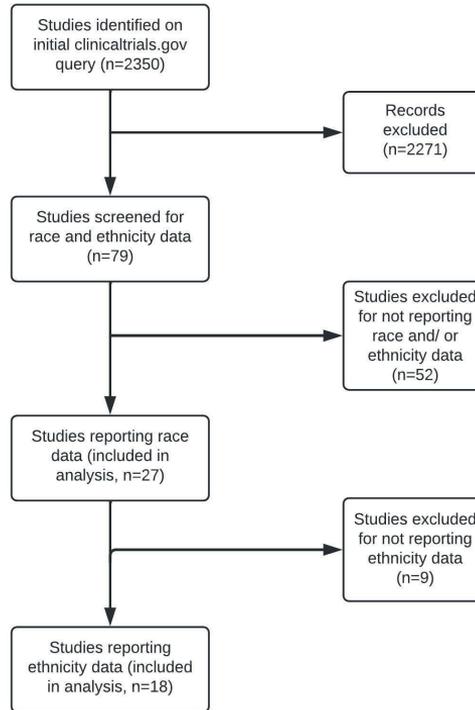
Aim of the study

- The aim of this study was to assess the current state of racial and ethnic representation in transarterial treatment trials for hepatocellular carcinoma
- For the assessment, we compared completed US-based clinical trials with race and ethnicity data to the current United States hepatocellular carcinoma population.

Methods

- The clinicaltrials.gov registry was queried for completed US-based clinical studies evaluating the use of transarterial therapies for hepatocellular carcinoma in January 2022.
- A broad list of keywords was developed using clinicaltrials.gov search terms and synonyms. The keyword list is available on reasonable request to the presenter.
- The incidence of HCC per year for each ethnic and racial subgroup was obtained from the SEER database and adjusted to calculate the HCC prevalence for each year by using the US Census Bureau data

Study flowchart



Results

- Only 27/79 (34.2%) studies had appropriate data for race reporting which enrolled a total of 1964 participants and only 18/79 (22.8%) studies had appropriate data for ethnicity reporting which enrolled a total of 990 participants.
- The type of study ($p=0.26$) or funding of funding did not affect reporting of race and ethnicity ($p=0.48$) [See next table]

Results

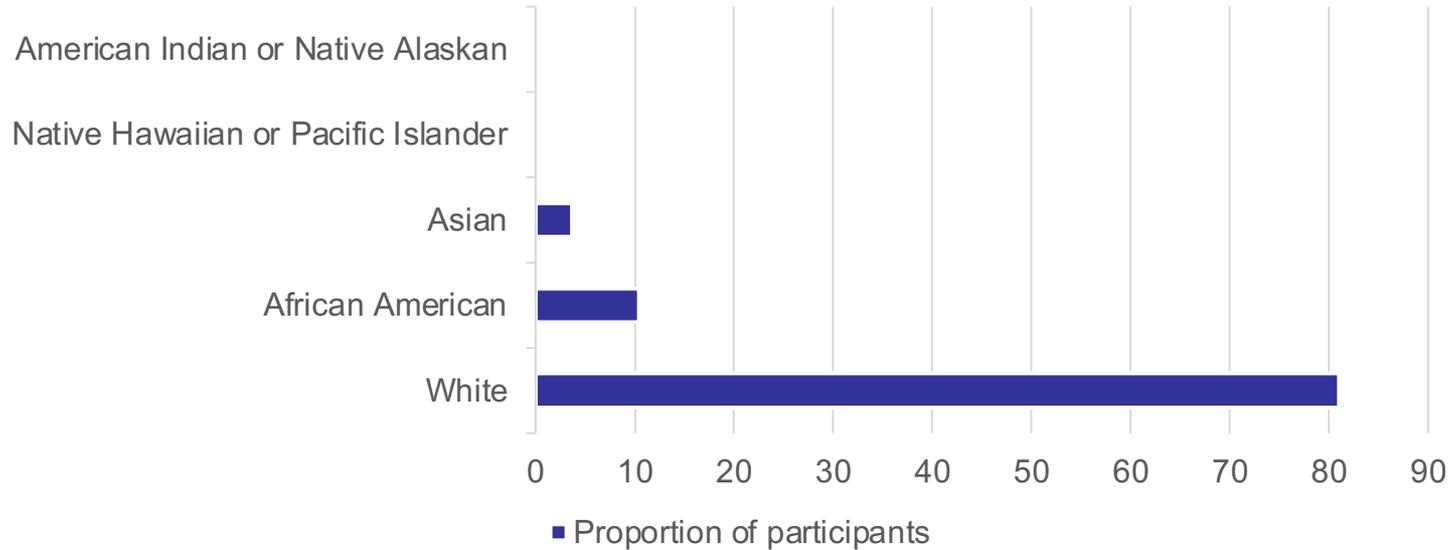
	Included studies (n=27) (number, %)	Excluded studies# (n=52) (number, %)	p-value
Study Phase			
Phase 1	8 (30)	19 (37)	0.26
Phase 1 Phase 2	2 (7)	1 (2)	
Phase 2	12 (44)	17 (33)	
Phase 3	2 (8)	8 (15)	
Phase 4	1 (4)	0 (0)	
Other	2 (8)	7 (13)	
Funder			
NIH [§]	11 (41)	16 (31)	0.48
Other	16 (59)	36 (69)	

#Excluded on the basis of absence of racial and ethnic reporting

[§]NIH: National Institutes of Health

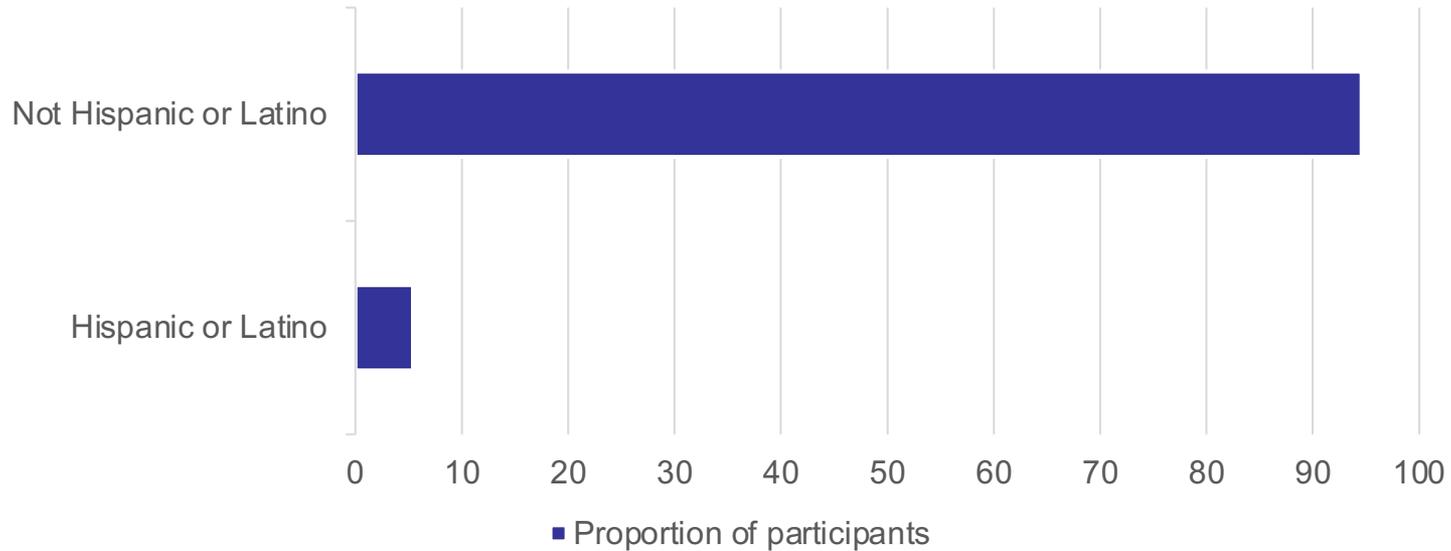
Results

Proportion of participants by race



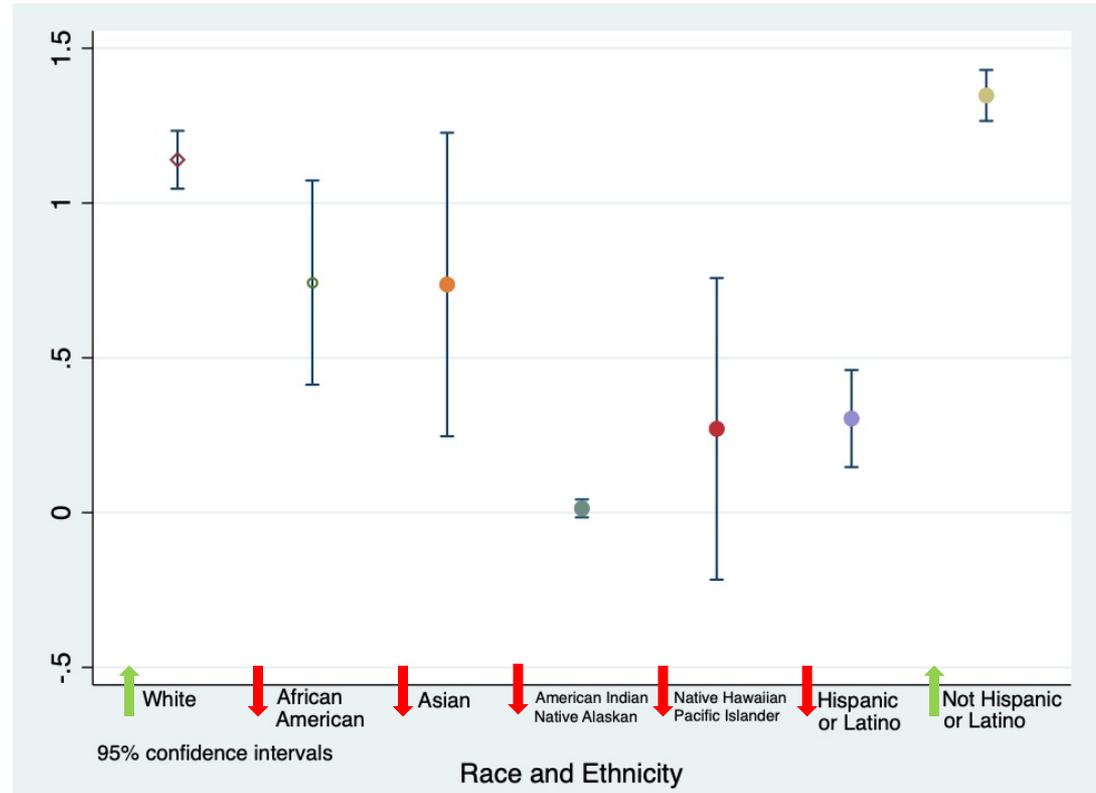
Results

Proportion of participants by ethnicity



Observed to expected ratios by race and ethnicity

↑ Overrepresented
↓ Underrepresented



Discussion

- When designing future studies appropriate representation of different racial and ethnic groups should be considered and detailed reporting of participants in different racial and ethnic groups should be provided.
- A multi-pronged approach needs to be employed to increase the diversity of participants enrolled in hepatocellular carcinoma clinical trials.

Conclusion

- In completed clinical trials of transarterial therapies for the management of hepatocellular carcinoma, racial and ethnic minorities were underrepresented, and the majority of the studies identified failed to report the racial and ethnic makeup of their participants.