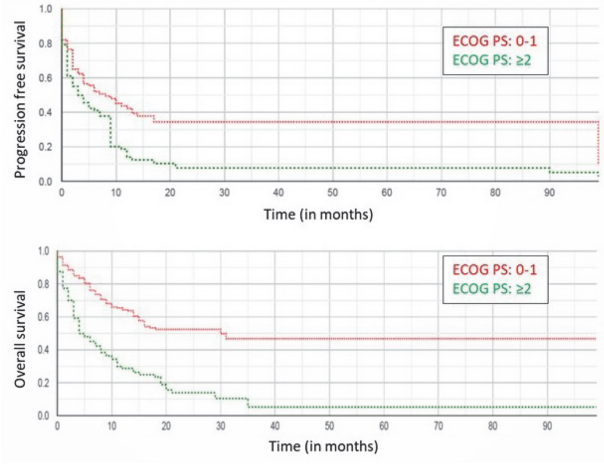
Methods We reviewed the medical records of 341 patients with NSCLC receiving immunotherapy as between July 2013 and June 2018. Progression-free survival and overall survival was calculated using Kaplan-Meier curve.

Results The average age of patients was 66 years (range: 39–90 years), with a male predominance (57%). Majority of the patients were Caucasian (87%), followed by African-American (12%), and Asian (1%). Most of the patients were former smoker (72%), followed by current smoker (19%) and never smoker (7%). Adenocarcinoma and squamous cell carcinoma was diagnosed in 206 (60%) patients and 112 (33%) patients, respectively. The ECOG-PS was 0, 1, 2 and 3 in 46 (13%), 175 (51%), 86 (25%) and 34 (10%), respectively. Four different immunotherapies were used, namely atezolizumab in 10 (3%), durvalumab in 34 (10%), nivolumab in 152 (44%) and pembrolizumab in 144 (42%) patients. Average number of cycles of atezolizumab received by the patient was 6 (range 2–22 cycles), durvalumab 15 (range 1–29 cycles), nivolumab 11 (range 1–112 cycles), and pembrolizumab 12 (range 1–52 cycles). Patients were grouped in good performance status (ECOG 0–1) and poor performance status (ECOG ≥2). The median progression free survival (PFS) was 7 months (95% CI 6.3–8.2) in patients with good PS and 3 months (95% CI 1.8–4.6) in patients with poor performance status ($p<0.001$). The median overall survival (OS) for patients with good performance status was 30 months (95% CI 16.6–42.3) and 4 months (95% CI 3.2–8.1) in patients with poor PS (figure 1). Adverse effects were recorded in a total of 83 (24%) patients, 18 (5%) patients had ECOG-PS 0, 50 (14%) patients had ECOG-PS 1, 18 (4%) patients had ECOG-PS 2 and 3 (1%) patients had ECOG-PS of 3. Most common adverse effects were pneumonitis (28%), diarrhea (8%) and hypothyroidism (8%).



Abstract 221 Figure 1 Progression free survival (PFS) and overall survival (OS) in patients with good performance status (ECOS PS 0–1) and poor performance status (ECOG ≥2) treated with immunotherapy in NSCLC

Conclusions Our data suggests that while the patients with poor PS tolerated the immunotherapy. However, poor PS was associated with significantly lower PFS and OS. Further studies are required to evaluate the effect of PS on survival in front-line immunotherapy.

Acknowledgements We thank Dr. Saqib Abbasi for helpful discussions.

Trial Registration N/A

Ethics Approval The study was approved by the Institution Review Board at KUMC, #CR00009003.

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N/A

http://dx.doi.org/10.1136/jitc-2020-SITC2020.0221

222 INCREASED PD-L1 TUMOR EXPRESSION CORRELATES WITH HIGH RATE OF RESPONSE TO PD-1 INHIBITORS IN PATIENTS WITH UNRESECTABLE, RECURRENT, AND METASTATIC CUTANEOUS SQUAMOUS CELL CARCINOMA

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Background PD-1 inhibitors were approved for locally advanced and metastatic cutaneous squamous cell carcinoma (CSCC) in 2019.[1] The identification of tumor characteristics that predict potential responders to immune checkpoint inhibitors (ICI) is an area of ongoing research. Here we present a series of consecutive patients with locally advanced, recurrent, or metastatic CSCC treated with PD-1 inhibitors and analyze tumor and blood genomics as well as PD-L1 expression with the aim of correlating with treatment response.

Methods We analyzed cases of CSCC treated with single agent PD-1 inhibitors in the last 2 years at Wake Forest. Demographic and outcome data were collected. Tumor tissue, whenever available, was tested for PD-L1, TMB, MSI, and genetic mutations. Blood was tested for circulating tumor at the beginning of treatment and at the time of maximum response.

Results Fourteen patients with CSCC treated with PD-1 ICI were included in this study. Six had locally advanced disease, seven had recurrent locally advanced disease, and one had metastatic disease. Four patients received treatment for >12 months and all had complete response (CR). Five patients had 6–12 months of treatment and all had near CR (pending imaging studies and ctDNA to confirm). Three patients had <6 months of treatment and had partial response (PR). Two of the patients had progressive disease, although one with possible pseudoprogression based on review of post-treatment surgical pathology specimen. Treatment was well tolerated with no immune related side-effects except one case of grade I hypothyroidism. Eleven patients had sufficient tumor tissue for genomic and PD-L1 testing. Initial blood genomic testing was performed in 12 of 13 patients and in follow up in patients who achieved maximum response. Patients with CR had PD-L1 of at least 30%. The additional tested patients had PD-L1 above 10%. The most frequently mutated gene was TP53 present in tumor in all tested patients and in blood in 6 patients, followed by NOTCH1/2 detected in the tumor of 10 of 11 patients tested. TMB was intermediate/high in tested patients except in the only patient who presented clear tumor progression.

Conclusions Treatment of locally advanced, recurrent, and metastatic CSCC with ICI led to a dramatic change in the management and prognosis of CSCC. Our series of patients with CSCC had a higher than reported rate of response. This corresponded with high TP53 alterations, NOTCH 1/2 alterations, high/intermediate TMB, and high level of expression of PD-L1. PD-L1 rates were higher than previously published.[1 2]

Ethics Approval The study was approved by Wake Forest University Institution's Ethics Board, approval number IRB00056249.

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http://dx.doi.org/10.1136/jitc-2020-SITC2020.0222

223 RACIAL DIFFERENCES IN OUTCOMES FOR METASTATIC RENAL CELL CARCINOMA (MRCC) PATIENTS MANAGED ON IMMUNE-CHECKPOINT INHIBITOR (ICI) THERAPY

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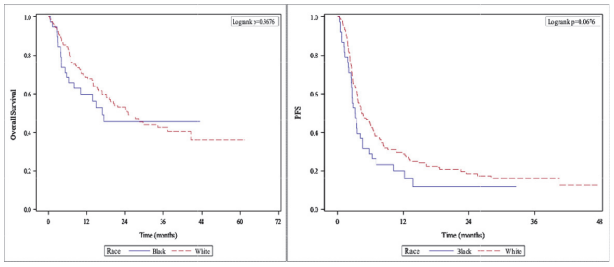
Background Immune checkpoint inhibitors (ICIs) have increased in prevalence for the treatment of metastatic clear-cell renal cell carcinoma (mccRCC) in recent years given their efficacy and favorable toxicity profile. However, there has been insufficient investigation in the literature of how clinical outcomes differ on the basis of race. In this paper, we investigated differences in clinical outcomes between African American (AA) and Caucasian mRCC patients treated with ICI therapy.

Methods We performed a retrospective study of 198 patients with mRCC who received ICI at the Emory Winship Cancer Institute from 2015–2020. Clinical outcomes were measured by overall survival (OS), progression-free survival (PFS), and clinical benefit (CB). OS and PFS were calculated from ICI-initiation to date of death and radiographic or clinical progression, respectively. CB was defined as a best radiographic response of complete response, partial response, or stable disease maintained for at least 6 months per response evaluation criteria in solid tumors version 1.1. The association of self-identified race with OS and PFS was generally modeled by Cox proportional hazards model. Univariable and multivariable logistic regression models were used for binary outcomes of CB. The univariate association of immune-related adverse events (irAEs) and non-clear-cell RCC (nccRCC) with race was assessed using Chi-square test.

Results Our cohort was made up of 38 AA (19%) and 160 Caucasian (81%) patients. Most of the patients were diagnosed with ccRCC (78%) and more than half received PD-1 monotherapy (57%). Most patients were international mRCC database consortium (IMDC) intermediate (57%) or poor-risk (25%) groups. AA patients displayed significantly shorter PFS (HR=1.52, 95% CI: 1.01–2.3, p=0.045) and trended towards decreased CB (OR=0.51, 95% CI: 0.22–1.17, p=0.111) in MVA (table 1). There was no difference in OS (HR=1.09, 95% CI: 0.61–1.95, p=0.778) between the two racial groups in MVA (table 1). On Kaplan-Meier method, AA patients had shorter median OS (17 vs 25 months, p=0.3676) and median PFS (3.1 vs 4.4 months, p=0.0676) relative to Caucasian patients (figure 1). Additionally, AA patients more commonly had nccRCC compared to Caucasian patients (41.7% vs 17.5% nccRCC, p-0.002). AA patients also trended towards a lower incidence of irAEs compared to Caucasian patients in UVA (23.7% vs 35.8%, p=0.153).

Abstract 223 Table 1
*MVA controlled for age, race, gender, IMDC risk group, number of prior lines of therapy, PD-1 monotherapy, and ccRCC
**statistical significance at alpha < 0.05

Variable (Race)	OS		PFS		CB	
	HR (CI)	p-value	HR (CI)	p-value	OR (CI)	p-value
African American (Black) [n=38]	1.09 (0.61-1.95)	0.778	1.52 (1.01-2.3)	0.045**	0.51 (0.22-1.17)	0.111
	Median OS: 17 months		Median PFS: 3.1 months		CB Rate: 35%	
Caucasian (White) [n=160]	1	-	1	-	1	-
	Median OS: 25 months		Median PFS: 4.4 months		CB Rate: 47%	



Abstract 223 Figure 1 African-American (black) and Caucasian (white) for OS (left panel) and PFS (right panel)

Conclusions In this group of mRCC patients treated with ICI, African American patients had significantly shorter PFS compared to Caucasian patients. These findings suggest race could play a role in the management of late-stage mRCC. Larger, prospective studies are needed to validate these findings.

Acknowledgements Research reported in this publication was supported in part by the Breen Foundation and the Biostatistics Shared Resource of Winship Cancer Institute of Emory University and NIH/NCI under award number P30CA138292. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Trial Registration Not applicable.

Ethics Approval This retrospective study was approved by the Emory University Institutional Review Board.

Consent Not applicable.

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Not applicable

http://dx.doi.org/10.1136/jitc-2020-SITC2020.0223

224 OUTCOMES OF STAGE IV MELANOMA IN THE ERA OF IMMUNOTHERAPY: A NATIONAL CANCER DATABASE (NCDB) ANALYSIS

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Background Immunotherapy (IO) has revolutionized the treatment landscape for metastatic melanoma and is now the mainstay of treatment since the approval of ipilimumab in 2011 and anti-PD-1 therapies (nivolumab and pembrolizumab) in 2015. The majority of data stems from trials that have