478 REAL-WORLD OUTCOMES IN PATIENTS WITH PENILE SQUAMOUS CELL CARCINOMA (PSCC) RECEIVING IMMUNE CHECKPOINT INHIBITORS (ICI)

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Background Penile squamous cell carcinoma (pSCC) is a rare and aggressive neoplasm with poor outcomes in advanced settings and limited treatment options beyond TIP chemotherapy (paclitaxel/ifosfamide/cisplatin). We evaluated real-world outcomes in patients treated with immune checkpoint inhibitors (ICI) for pSCC.

Methods We performed a retrospective review of patients with pSCC who received ICI from 2012-2022 at the Winship Cancer Institute at Emory University. Clinical benefit was defined as complete response, partial response, or stable disease based on RECIST 1.1 criteria. Overall survival(OS) and progression-free survival(PFS) were assessed by Kaplan-Meier method and univariate Cox regression(UVA).

Results Of 21 patients, 71.4% were white, 28.6% were black. Median age at diagnosis was 55 years (37-82). The majority (65%) had ECOG performance status ≥2. Most common histological subtype was keratinizing (42.9%). Eight of 9 (89%) patients were HPV+. Median tumor size was 6.75cm (0.30-19.5). At diagnosis, 4.8%/33.3%/61.9% were stage 2/3/4 respectively. Eight patients had initial distal metastases. At ICI initiation, the median level of C-reactive protein was 43.1 µg/mL (0-201.9), lactate dehydrogenase: 140.5 units/L (99-414), and neutrophil-to-lymphocyte ratio (NLR): 6.87 (2.49-45.46). Seven of 11 patients (63.6%) were PD-L1+. Median follow-up was 8.16 months(mo) and median time to ICI treatment from diagnosis was 15.6mo. Median OS and PFS for overall cohort were 8.2mo and 1.9mo respectively. Median OS was 8.4mo in white patients and not reached(NR) in black patients (1.3, NA). Median PFS was 2mo in white patients and NR in black patients (0, NA). On UVA, no differences were seen in outcomes with respect to race (figures 1,2) and PD-L1 status (figures 3,4). Three patients (14.3%) had clinical benefit and 76.2% progressed post-ICI. Only 14.3% were alive at last contact. Nearly all patients previously received chemotherapy. ICI was 1st line(1L) in 1 patient(4.8%), 2L in 13(61.9%), 3L in 6(28.6%), 4L in 1(4.8). Monotherapy with nivolumab or pembrolizumab was the most common regimen, others included combination ICI, cemipilimab, or clinical trial. Two patients received a second ICI regimen. Sites of progression included local invasion (66.7%), lymphadenopathy (57.1%), retroperitoneum (47.6%), lung (42.9%), and bone (42.9%). Three patients (14.3%) developed grade 3/4 ICI-related adverse events. Higher NLR and larger resection size were associated with shorter OS (table 1).

Conclusions Our real-world analysis confirms poor response rates of pSCC to ICI in an unselected approach and the critical need for biomarkers. NLR may be a potential biomarker to assess ICI response in pSCC. More prospective and multicenter studies are needed for confirmation.

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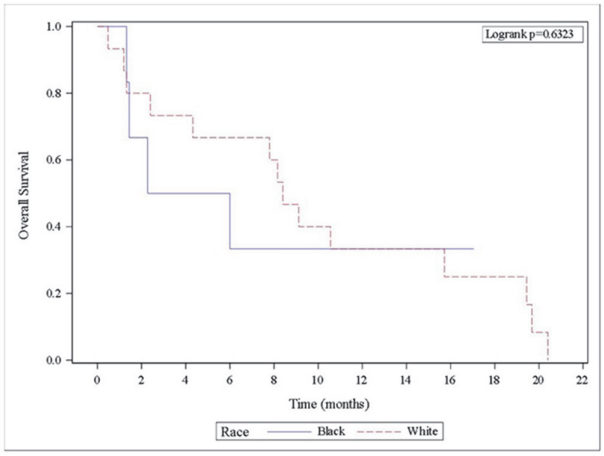
Ethics Approval This study was approved by Emory's institution's Ethics Board; approval number 5355-21.

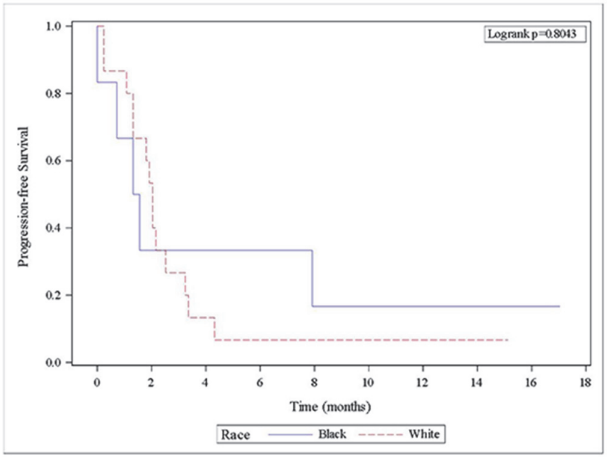
Figure 1



Race	No. of Subject	Event	Censored	Median Survival (95% CI)
Black	6	4 (67%)	2 (33%)	4.1 (1.3, NA)
White	15	14 (93%)	1 (7%)	8.4 (1.3, 15.7)

Abstract 478 Figure 1 Kaplan-Meier curve of OS stratified by race. No significant difference in OS was observed between white and black patients (p=0.6323).

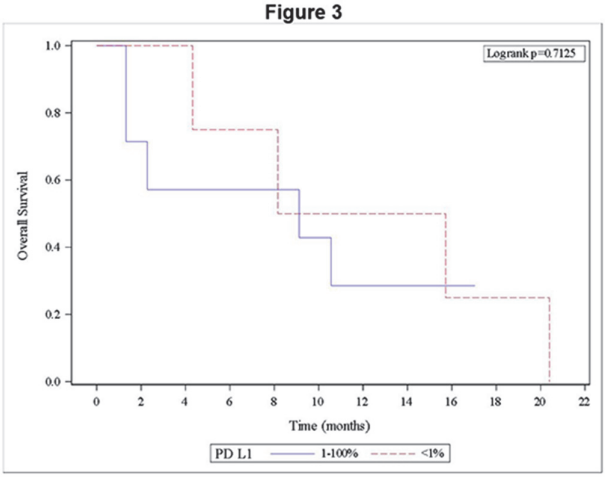
Figure 2



Race	No. of Subject	Event	Censored	Median Survival (95% CI)
Black	6	5 (83%)	1 (17%)	1.4 (0, NA)
White	15	14 (93%)	1 (7%)	2 (1.1, 2.5)

Abstract 478 Figure 2 Kaplan-Meier curve of PFS stratified by race. No significant difference in PFS was observed between white and black patients (p=0.8043).

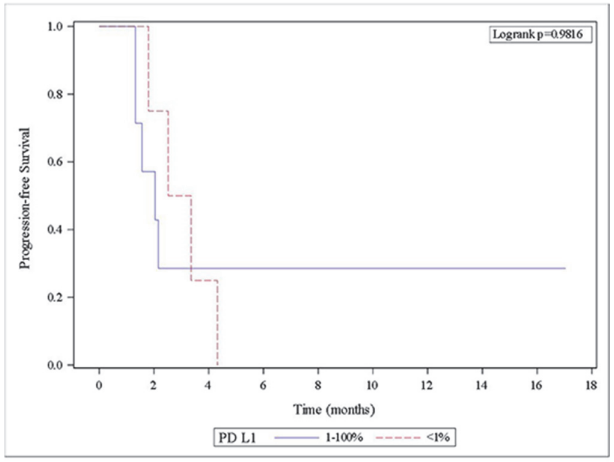
Figure 3



PD L1	No. of Subject	Event	Censored	Median Survival (95% CI)
1-100%	7	5 (71%)	2 (29%)	9.1 (1.3, NA)
<1%	4	4 (100%)	0 (0%)	11.9 (4.3, 20.4)

Abstract 478 Figure 3 Kaplan-Meier curve of OS stratified by PD-L1. No significant difference in OS was observed between PD-L1+ and PD-L1 (-) patients (p=0.7125)

Figure 4



PD L1	No. of Subject	Event	Censored	Median Survival (95% CI)
1-100%	7	5 (71%)	2 (29%)	2 (1.3, NA)
<1%	4	4 (100%)	0 (0%)	2.9 (1.8, 4.3)

Abstract 478 Figure 4 Kaplan-Meier curve of PFS stratified by PD-L1. No significant difference in PFS was observed between PD-L1+ and PD-L1 (-) patients (p=0.9816).

Abstract 478 Table 1 Tabulated OS and PFS by NLR and resection size at ICI initiation.
Higher NLR and higher resection sizes were associated with decreased overall survival.

Table 1. Tabulated OS and PFS by NLR and resection size at ICI initiation.

Covariates	PFS UVA		OS UVA	
	HR	p-value[a]	HR	p-value
NLR[b]	1.08 (95% CI: 1.03-1.15)	**0.006**	1.10 (95% CI: 1.04-1.19)	**0.008**
Resection size (cm)[b]	1.06 (95%CI: 0.93-1.17)	0.366	1.15 (95% CI: 1.00-1.30)	**0.042**

[a]Statistical significance at alpha <0.05.
[b]NLR and resection size were treated as continuous variables.

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