Prevalence of PD-L1 and other selected biomarkers in advanced urothelial, advanced esophageal carcinoma and advanced head and neck squamous cell carcinoma in two reference institutions of Colombia

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Background and rationale

For most patients in Colombia with solid tumors and advanced disease treatment options are limited. First-line chemotherapy is the most used therapeutic strategy in advanced solid tumors such as: Head and Neck Squamous Cell Carcinoma (HNSCC), esophageal cancer (EC), and urothelial carcinoma (UC). Therapeutic options have been limited for these patients, and recent introduction of immunotherapy has improved the treatment landscape, complementing the standard approaches in all lines of metastatic treatment.

Characterization of PD-L1 expression in this population will allow us to have a better profile of our country's biomarker characteristics. Currently published data suggest that immune therapy with anti PD-1 agents is becoming an important therapy option in solid tumors. For some cancers, anti PD-1 therapy efficacy is associated with tumor PD-L1 expression.

PD-L1 expression is predictive of overall survival with check point inhibitors therapy in many types of solid tumors [1], and PD-L1 expression testing can help guide physician patient care decisions[2]. On the other hand, there are no data in the Colombian population that describe the PD-L1 expression pattern in HNSCC, EC, and UC.

Objectives

1. To characterize the level of PD-L1 expression in advanced HNSCC, advanced EC, and advanced UC in archived tissue samples of Colombian patients in two reference cancer institutions.

2. To evaluate expression of other biomarkers relevant in solid tumors: Human Papilloma Virus (p16) for HNSCC (only for tumors located in oropharyngeal sites) and HER2 (Data regarding level of HER2 expression in EC will be collected only if available in the medical records).

Methodology

Observational, retrospective and descriptive study to examine PD-L1 protein expression in archived tumor samples from subjects with advanced HNSCC, advanced EC, advanced UC, in samples from two Colombian reference cancer institutions. Positive PD-L1 expression level was measured by immunohistochemistry(IHC) using Combined Positive Score (CPS).

PD-L1 expression in all tissue samples was performed with a validated IHC method using Dako 22C3. Antibody P16 protein assessment for HPV was performed using immunohistochemistry.

Information on demographic, pathology, treatment, other biomarkers such as HER2 expression were collected from the existing electronic medical record system of the institution

Two oncological institutions were included in this study: Fundación Valle del Lili in Cali, Colombia and Fundación para la Investigación Clínica y Molecular Aplicada al Cáncer (FICMAC) located in Bogota, Colombia.

Methodology: outcomes of interest

1. Frequency and proportion regarding the level of PD-L1 expression in the tissue samples from patients with diagnosis of advanced HNSCC, advanced EC, and advanced UC from the two oncology institutions selected.

2. Frequency and proportion of patient samples positive for HPV in HNSCC located in oropharyngeal sites. Frequency and proportion of patient samples positive for HER2 expression in EC.

Results

A total of 181 tissue samples were collected across the three tumor indications for biomarker testing (100 of HNSCC, 22 of EC, and 59 samples of UC). Sample demographics is summarized in **Table 1.**

A total of 27% of the HNSCC samples had PD-L1 CPS of 20 or more and 73% had PD-L1 CPS of 1 or more **(Table 2)**. In this same population 47% of the samples were P16 positive **(Figure 1A)**. HER2 data expression were found on the records for only 41% of cases in the esophageal tumors group, HER2 was positive in 23% of these cases. **(Figure 1B)**.

Regarding the EC samples, 22,7% had PD-L1 CPS of 10 or more and 40,9% had PD-L1 CPS of 1 or more **(Table 2)**.

On the other hand, the 22% of the UC samples had PD-L1 CPS of 10 or more and 54,2% had PD-L1 CPS of 1 or more **(Table 2)**.

Table 1. Demographic and clinical characteristics of the patients at baseline.

Characteristic	Head & Neck Squamous Cell Carcinoma (N=100)	Esophageal cancer (N=22)	Urothelial Carcinoma (N=59)
Median Age (IQR) - yr	61.5 (53.0-70.0)	67.5 (64.0-77.3)	72.0 (68.0-80.0)
Sex - no. (%)			
Female	21 (21.0%)	2 (9.1%)	13 (22.0%)
Male	79 (79.0%)	20 (90.9%)	46 (78.0%)
Type of insurance - no. (%)			
Contributory	67 (67.0%)	16 (72.7%)	47 (79.7%)
Subsidized	18 (18.0%)	2 (9.1%)	4 (6.8%)
Others	15 (15.0%)	4 (18.1%)	12 (13.6%)
Place of residence - no. (%)			
Rural	4 (4.0%)	1 (4.5%)	2 (3.4%)
Urban	96 (96.0%)	21 (95.5%)	57 (96.6%)
BMI - no. (%)			
Underweight	12 (12.0%)	3 (13.6%)	5 (8.5%)
Normal	53 (53.0%)	15 (68.2%)	32 (54.2%)
Overweight	27 (27.0%)	3 (13.6%)	19 (32.2%)
Obesity	7 (7.0%)	1 (4.5%)	3 (5.1%)
No data	1 (1.0%)	0 (0.0%)	0 (0.0%)
ECOG - no. (%)			
0	55 (55.0%)	13 (59.1%)	43 (72.9%)
1	43 (43.0%)	7 (31.8%)	10 (16.9%)
2	0 (0.0%)	2 (9.1%)	3 (5.1%)
3	1 (1.0%)	0 (0.0%)	0 (0.0%)
4	0 (0.0%)	0 (0.0%)	3 (5.1%)
No data	1 (1.0%)	0 (0.0%)	0 (0.0%)
Disease stage at initial diagnosis - no. (%)			
I	7 (7.0%)	0 (0.0%)	16 (27.1%)
II	5 (5.0%)	5 (22.7%)	12 (20.3%)
III	15 (15.0%)	13 (59.0%)	22 (37.3%)
IV	69 (69.0%)	4 (18.2%)	9 (15.3%)
No data	4 (4.0%)	0 (0.0%)	0 (0.0%)

Disclosure
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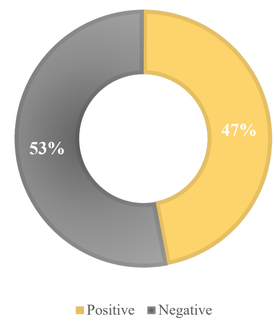
Results

Table 2. PD-L1 expression by tumor

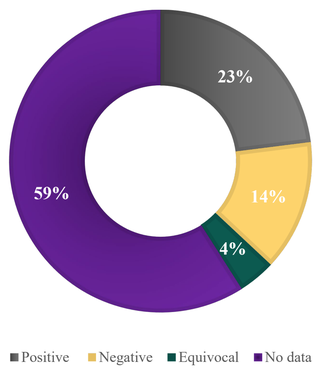
Tumor Type & PD-L1 CPS cut-off	Percentage (%)
HNSCC CPS ≥20	27.0
HNSCC CPS ≥1	73.0
UC CPS ≥10	22.0
UC -CPS ≥1	54.2
EC CPS ≥1	40.9
EC CPS ≥10	22.7

Figure 1. P16 (A) and HER2 (B) expression in HNSCC and EC samples respectively

A.) P16 expression



B.) HER2 expression



Conclusions

The PD-L1 expression prevalence in a cohort of the Colombian population has been studied for the first time. The prevalence of PD-L1 CPS score ≥10 for UC and EC, and of CPS ≥ 20 for HNSCC, was lower than previously reported in other clinical trials[3,4,5]. Additionally, a high expression of p16 was found in those tumors, which supports the existing evidence regarding the role of HPV in the pathophysiology of this disease. This initiative helps to have a better understanding of biomarker behavior in Colombian patients influenced by their own environment and genetics.

References

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