A retrospective observational multicenter study on skin toxicities induced by Cemiplimab

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Background

Cutaneous toxicities due to oncological therapies are a common scenario in daily clinical practice and have gained new importance with the advent of immunotherapy (1).

Methods

This is a **retrospective observational study** collecting the data of **120 patients** affected by **advanced cutaneous squamous cell carcinomas** (CSCCs), located in different body areas, **treated with Cemiplimab**. Seven different Italian centers were involved between 2019 and 2022.

All the possible **skin toxicities** were recorded according to the CTCAE version 5.0. Data on clinical outcome were also collected. Kaplan-Meier (KM) curves were carried out for overall survival (OS) and progression-free survival (PFS).

Results

Our study showed that the CSCCs were located in the great majority of cases in the **head and neck region** (65.8%) and on the **upper or lower arms** (20.0%).

Males were more often involved than females (62.5% vs 37.5%) and the median age of the patients was about **80 years** (range: 19.5-98.8). Of the 120 enrolled patients, 107 (90.8%) did not present any skin toxicity, while **11 patients (9.2%) presented a skin toxicity**.

The list of these adverse events included **skin rash, alopecia areata, itch, autoimmune bullous disease, psoriasis, nummular eczema**. In most of these patients, the treatment of choice was a corticosteroid therapy, topical or systemic, with resolution or at least improvement/stabilization.

Fifty-three patients (44.6%) interrupted the treatment and the causes of **treatment interruption** were: progressive disease (58.5%), death (17.0%), non-cutaneous toxicities (9.4%), patient's decision (5.7%), **cutaneous toxicities (1.9%)**, other comorbidities (1.9%), other causes (5.7%).

Confirmed progression of disease was observed in 40 patients. The best objective response was calculated and **disease control rate** (complete response + partial response + stable disease) **was observed in 78 of 95 evaluable patients (82.1%), of which 68 did not have cutaneous toxicities**.

The median PFS was 21.9 months (95%CI: 11.7-Not estimable), while the 12-months OS was 69.0% (95%CI: 58.4-77.4).

Conclusion

Skin toxicities are uncommon in patients receiving Cemiplimab for advanced cutaneous squamous cell carcinoma. In our study, only 10.8% of patients developed this type of adverse event and cutaneous toxicities were the cause of treatment interruption in a minority of cases, precisely 1.9%.

The presence of a skin toxicity is not an independent predictor at the multivariate level associated to progression free survival and overall survival. A clear association between skin toxicities due to Cemiplimab treatment and drug activity and effectiveness parameters was not observed, probably because of the low number of patients enrolled in the study. **Further larger studies are needed on this topic.**

Table 1. Response by the presence of cutaneous toxicities

Best response on evaluable patients	Total	
	Pts without cutaneous toxicities N (%)	Pts with cutaneous toxicities N (%)
Disease control rate (CR+PR+SD)	68 (80.0)	10 (100.0)
Progressive Disease	17 (20.0)	0 (0.0)

Figure 1. KM curve for PFS

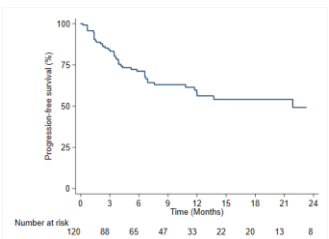
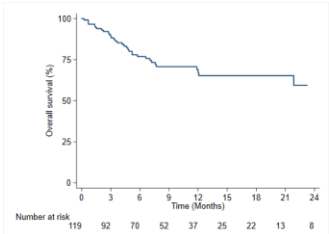


Figure 2. KM curve for OS



Keywords

Cemiplimab, anti-PD1, advanced cutaneous squamous cell carcinoma, skin toxicities, cutaneous side effects.

References

(1) Valentin J et al. Real world safety outcomes using cemiplimab for cutaneous squamous cell carcinoma. J Geriatr Oncol. 2021; 12: 1110-1113.