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A retrospective observational multicenter study on cutaneous adverse events induced by Cemiplimab.

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Background. Cemiplimab is an anti-PD1 drug approved for locally advanced and metastatic cutaneous squamous cell carcinoma.

Methods. We report here the results of a retrospective observational study collecting the data of **120 patients affected by locally advanced cutaneous squamous cell carcinomas** treated with cemiplimab.

All possible cutaneous adverse events were recorded according to the Common Terminology Criteria for Adverse Events version 5.0. Data on clinical outcome were also collected. Univariable and multivariate models were carried out for overall survival and progression-free survival.

Results. Of the 120 enrolled patients, 107 (90.8%) did not present any cutaneous adverse event during treatment, while **11 patients (9.2%) presented a cutaneous adverse event**. The list of these adverse events, that occurred after a time that was variable from 1 to 24 months, included **macular rash, alopecia areata, pruritus, autoimmune bullous disease, psoriasis, nummular eczema**. All the cutaneous adverse events observed were **grade 1 or 2**, except 1 bullous pemphigoid, that was reported as grade 4.

In most of these patients, the treatments of choice were oral antihistamines, topical or systemic corticosteroid therapy and the use of emollients, with resolution, improvement or stable disease (table 1).

The best objective response was calculated and disease control rate (complete response + partial response + stable disease) was observed in 78 patients (65.0%), of which 10 had at least one cutaneous adverse event. The median progression free survival was 21.9 months (95%CI: 11.7-Not estimable), while the 12-months overall survival was 69.0% (95%CI:58.4-77.4)

Conclusions. Cutaneous adverse events are uncommon in patients receiving cemiplimab and in our study pruritus was the most frequent one, followed by psoriasis and autoimmune bullous disease.

Our study suggests that the presence of a cutaneous adverse event is not an independent predictor associated to overall survival and progression-free survival, at a multivariate level.

Patient	Type	Grade	Therapy for the cutaneous AE	Months from start	Outcome
1	Rash	1	Oral corticosteroid therapy	1	Resolution
2	Alopecia	1	None	1	Stable
3	Autoimmune bullous disease	2	Oral and topical corticosteroid therapy	10	Improvement
4	Autoimmune bullous disease	4	Intravenous and topical corticosteroid therapy	5	Resolution
5	Nummular eczema	1	Oral and topical corticosteroid therapy	4	Improvement
6	Itch	1	Oral antihistamines, emollients	5	Improvement
7	Itch	1	Oral antihistamines, emollients	3	Stable
8	Itch	1	Oral antihistamines, topical corticosteroid therapy, emollients	4	Stable
9	Itch	2	Oral antihistamines, topical corticosteroid therapy, emollients	4	Improvement
10	Itch and psoriasis	2	Oral antihistamines, topical corticosteroid therapy	1	Resolution
11	Psoriasis	2	Topical corticosteroid therapy	24	Stable

TABLE 1

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