CEMIPLIMAB SAFETY IN PATIENTS WITH ADVANCED CUTANEOUS SQUAMOUS CELL (CSCC) AND NON-SMALL CELL LUNG CANCER (NSCLC). THE MD ANDERSON EXPERIENCE

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Introduction

The safety profile of Cemiplimab a newer Immune Checkpoint Inhibitor(ICI) remains limited given its recent FDA approval. Used in CSCC and NSCLC patients with advanced metastatic disease who are often frail and without curative intent therapy options. We aim to evaluate the safety profile of Cemiplimab in this susceptible population

Methods

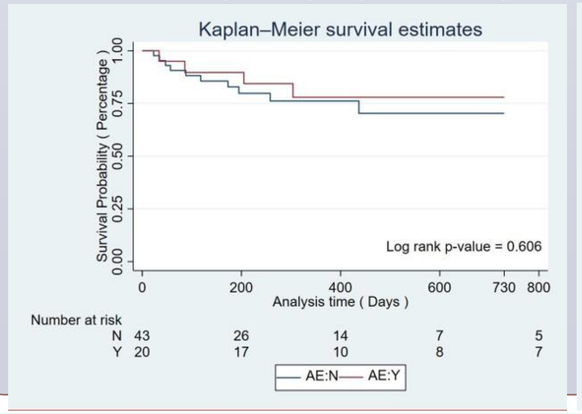
Retrospective, descriptive study. Under IRB protocol, the records of palliative patients who received Cemiplimab at our institution between 2018 and 2020 were reviewed, demographics and Immune related adverse events(irAE) data collected. Primary outcome was irAE's, and the secondary therapy response. Measures of association were used to compare the irAE's and no IrAE's groups. Obtained Kaplan Meier survival estimates and multivariable cox proportional hazard model for hazard ratios of an irAE

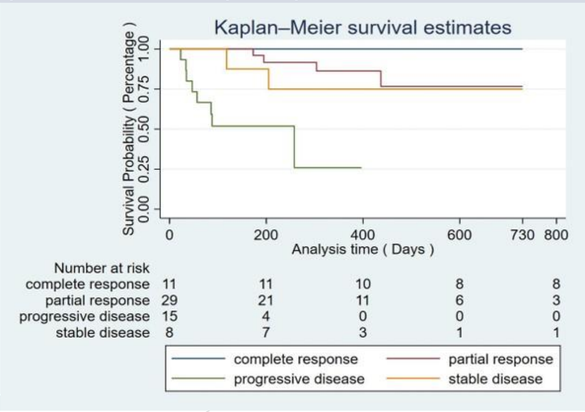
Results

	All Palliative patients n = 63	No irAE n = 43	IrAE n = 20	P-value
Age, years (mean ± SD)	73.9 ± 9.8	74.3 ± 9.2	73.1 ± 11.2	0.640
Gender, n (%) Male	53 (84.1)	34 (79.1)	19 (95)	0.107
Race / Ethnicity White	61 (96.8)	42 (97.7)	19 (95.0)	0.269
Smoking history, n (%)	35 (55.6)	25 (58.1)	10 (50.0)	0.545
Prior surgery, n (%)	42 (66.7)	25 (58.1)	17 (85.0)	0.035
Prior chemotherapy, n (%)	13 (20.6)	9 (20.9)	4 (20.0)	0.542
Prior immunotherapy, n (%)	2 (3.2)	1 (2.3)	1 (5.0)	0.573
Prior autoimmune disease history, n (%)	15 (23.8)	10 (23.3)	5 (25.0)	0.880
Prior radiotherapy, n (%)	30 (47.6)	21 (48.8)	9 (45.0)	0.777
Prior cutaneous adverse events, n (%)	2 (3.1)	1 (2.3)	1 (5.0)	0.573
Prior non cutaneous adverse events, n (%)	1 (1.6)	1 (2.3)	0 (0.0)	0.492

Table 1. Baseline demographics

63 patients identified, 20(31.7%) developed irAE. They were more likely to have had prior surgery (85 % vs 58.1 %, p=0.035), higher number of cemiplimab doses (IQR 5.5-25.5 vs 3-17, p=0.038), grade I adverse events 7(35%), grade II 9(45%), common organs affected, skin 5(25%), constitutional 5(25%), thyroid 4(20%), musculoskeletal 2(10%), only 1(5%) had multiorgan compromise, of the 24(72.7%) that received irAE treatment, 11(52.4%) was not systemic, and 18(54.5%) received supportive care, 7(35%) received steroids, no patients required immunomodulators, 14(70%) the irAE did not affected treatment dose, 7(33.3%) improved, 10(47.6%) resolved and 1(4.8%) died.





Most of the irAE's were minor including fatigue, pruritus, rash, except for 2 cases of bullous pemphigoid. Kaplan Meier curve showed Cemiplimab did not have a negative impact on survival, multivariable cox regression showed that prior history of autoimmune disease had HR of 12.6 of developing an irAE, p=0.018 and prior history of chemotherapy HR of 8.3, p=0.045

Conclusion

Cemiplimab had no new safety signals, and its side effect profile was similar to other anti-PD-(L)1 therapies. Half of the patients received supportive care, highlighting the important role of supportive and palliative care

References

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