**Cemiplimab for advanced cutaneous squamous cell carcinoma in kidney transplant recipients.**

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**ABSTRACT**

**Background:** Kidney transplant recipients (KTR) are at increased risk of cancer due to chronic immunosuppression. The cumulative incidence ratio of non-melanoma skin cancer has been estimated to be > 60% compared to the general population. Moreover, in solid organ transplant recipients (SOTR) these cancers have a more aggressive behavior, with an increased risk of metastasis and death. Cemiplimab, a human monoclonal IgG4 antibody against programmed cell death (PD-1) has shown considerable clinical activity in metastatic and locally advanced cutaneous squamous cell carcinoma (cSCC) in patients for whom no widely accepted standard of care exists. Cemiplimab has therefore been approved since 2018 for the treatment of advanced cSCC. However, data regarding the use of Cemiplimab in SOTR and particularly in KTR are scarce and based on published case reports and small case series. In this study, we report on the real-life outcome of cemiplimab use in a Belgian cohort of seven KTR suffering from advanced cSCC.

**Objective:** To report on the overall response rate (ORR) and safety of cemiplimab in KTR in Belgium.

**Results:** Seven patients suffering from advanced cSCC, treated with cemiplimab, between 2018 and 2022, in Belgium were identified. Three patients were on corticosteroid monotherapy, one patient on tacrolimus monotherapy and three patients were on at least 2 immunosuppressive treatments at start of cemiplimab therapy. The ORR was 42.8%, stable disease was seen in 14.3% and progressive disease was found in 42.8% of the patients, respectively. The median administered number of cycles was 12, interquartile range (IQR) 25-75 [3.5 – 13.5]. All patients were treated with surgery before administration of cemiplimab, 71.4% received additional radiotherapy and only 1 patient was treated with chemotherapy prior to receiving cemiplimab. Biopsy-proven acute renal allograft rejection was observed in one patient, who eventually lost his graft function but showed a complete tumor response to treatment. Low grade skin toxicity was seen in one patient of the cohort.

**Conclusion:** The present case series shows that the use of cemiplimab in KTR with advanced cSCC who failed to respond to conventional treatment is associated with an ORR of 42.8% with minimal risk of graft rejection (14.3%)
and good tolerance. Cemiplimab may therefore be a feasible treatment for KTR with advanced cSCC and this treatment should therefore not be withheld in this notoriously difficult to treat patient population.

Graphical abstract

Cemiplimab for advanced cutaneous squamous cell carcinoma in kidney transplant recipients.

Belgium
Multicentric (n=5)

7 patients with advanced cSCC

Eligible for cemiplimab after failure conventional treatment

Safety:
- Graft rejection - graft loss 14.3% (n=1)
- irAE in 14.3%, grade I-II skin toxicity (n=1)

Response rates:
- ORR in 42.8% (n=3)
- SD 14.3% (n=1)
- PD in 42.3% (n=3)
- Median overall survival was 12 months (95% CI 2 – 15 months)

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