**Background** Immune-related adverse events (irAEs) are serious side effects of immune checkpoint inhibitors (ICIs) for patients with advanced cancer. Understanding the epidemiology and risk factors for severe irAEs would be beneficial for patients and clinicians.

**Methods** We performed a retrospective review of cancer patients treated with ICIs using un-identifiable claims data from a nationwide US health insurance plan from January 3rd, 2011 to December 31st, 2019. Patients with an identified primary cancer and at least one administration of an ICI were included in the study. We defined severe irAE as any inpatient hospitalization with new immunosuppression within 2 years after initiation of ICI. The main outcomes were incidence of severe irAE in ICI therapy and factors associated with severe irAE occurrence. Multivariable logistic regression, including Charlson comorbidity index, age, gender, primary cancer, region, and zip code average income and unemployment, was used to model risk factors for severe irAE (table 1).

**Results** There were 14,378 patients followed over 19,177 patient-years identified with a primary cancer and at least 1 administration of an ICI. 504 (3.5%) patients developed a severe irAE. The incidence of severe irAEs per patient ICI treatment year was 2.6%, rising from 0% (0/71) in 2011 to 3.7% (93/2486) in 2016 (figure 1). Combination immunotherapy (OR: 2.44, p < 0.001) and younger age (OR: 0.77, p < 0.001) were associated with increased odds of developing severe irAEs, whereas patients with non-lung cancer were associated with decreased odds of irAEs (melanoma OR: 0.70, p = 0.01, renal cell carcinoma OR: 0.71, p = 0.03, other cancers OR: 0.50, p < 0.001; figure 1). Sex, region, zip code income, and zip-code imputed unemployment were not associated with severe irAE incidence. Prednisone (72%) and methylprednisone (25%) were the most common immunosuppressive treatments identified in irAE hospitalizations.

**Conclusions** We found that 3.5% of patients initiating ICI therapy experienced severe irAEs requiring hospitalization and immunosuppression. The odds of severe irAEs were higher with younger age, treatment with combination ICI therapy (CTLA-4 and PD-1 or PD-L1), and lower for other cancers compared with patients on PD-1 or PD-L1 inhibitors with lung cancer. This evidence from the first nationwide study of severe irAEs in the US identified the real-world epidemiology, risk factors, and treatment patterns of severe irAEs in the US which may guide treatment selection and decisions for patients and clinicians.
Background Immune checkpoint inhibitor (ICI) therapy has revolutionized cancer treatment and has become a standard of care. There are now numerous FDA approved indications for ICIs and an increasing number of patients receiving these treatments, which has led to an increase in the risk of immune-related adverse events (irAEs) including endocrinopathies. Diabetes mellitus is a rare irAE of ICI therapy with an approximate incidence of 1-2%. There is paucity of data in literature about incidence, characteristics and possible predictors. Diabetes mellitus is a rare irAE of ICI therapy with an approximate incidence of 1-2%. There is paucity of data in literature about incidence, characteristics and possible predictors.

Methods We conducted a retrospective chart review of patients who received ICI therapy at RPCCC and treated in the setting of ICI therapy, both commonly (pruritus, rash, vitiligo) and more rarely reported (scleroderma, urticaria). As nivolumab and pembrolizumab currently make up the bulk of approvals for ICI therapy, this analysis of real-world irAE incidence will be of use to treatment teams to improve quality of life and ensure ICI therapy adherence. Furthermore, this analysis sets the stage for future in-depth investigation of these cutaneous toxicities, including dose-response relationships, prognostic information from cutaneous events, and optimal treatment strategies.

Ethics Approval This study did not require IRB approval, due to the use of anonymized and de-identified aggregate-level data.

Conclusions We report the frequency of dermatoses encountered in the setting of ICI therapy, both commonly (pruritus, rash, vitiligo) and more rarely reported (scleroderma, urticaria). As nivolumab and pembrolizumab currently make up the bulk of approvals for ICI therapy, this analysis of real-world irAE incidence will be of use to treatment teams to improve quality of life and ensure ICI therapy adherence. Furthermore, this analysis sets the stage for future in-depth investigation of these cutaneous toxicities, including dose-response relationships, prognostic information from cutaneous events, and optimal treatment strategies.

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