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Incidence of venous thromboembolism with immune checkpoint inhibitors in a community setting: A single-center retrospective study.

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Background: Immune activation and inflammation caused by immune checkpoint inhibitors (ICIs) are critical pathobiological drivers for venous thromboembolism (VTE). There is a paucity of data about VTE risk in cancer patients receiving ICI. We aimed to describe the incidence of VTE in cancer patients receiving ICI in a community setting. **Methods:** We conducted a single center, retrospective cohort study at Saint Vincent Hospital. The study cohort was created using our center's pharmacy database of patients who received any of the five ICIs (ipilimumab, nivolumab, pembrolizumab, atezolizumab, or durvalumab) between Jan 2017 and Dec 2022. VTE events including deep venous thrombosis, splanchnic vein thrombosis, and pulmonary embolism, were identified by chart review. We used a self-controlled risk-interval design, with "control period" and "at-risk period" being 6 months before and after the initiation of ICI treatment respectively. VTE events were also analyzed for subgroups: Single-agent ICI therapy (IA), Dual ICI therapy (IB), and ICI + chemotherapy (IC). Descriptive statistics and cox regression were used for statistical analysis. **Results:** Study population included 170 patients, with 75, 14, and 81 patients in subgroups IA, IB, and IC respectively. The mean age of the patients was 69.51 $\pm$ 10.05 years with a majority being males (62.4%). The most common cancer observed was non-small cell lung cancer (43.5%) followed by small cell lung cancer (6.9%), and malignant melanoma (5.7%). Pembrolizumab (55.3%) was the most common ICI used and nivolumab + ipilimumab (7.64%) was the most common dual ICI used. We noted a 1.25-fold higher incidence of VTE post-ICI use (Incidence rate ratio [IRR]: 11.76 per 100 person-year) compared to pre-ICI use (IRR: 9.41 per 100 person-year) at 6 months. On subgroup analysis, Group IB had the highest risk for VTE at 6 months (IRR: 28.57 per 100 person-year), followed by group IC and IA (IRR: 14.12 and 8.0 per 100 person-year respectively). IRR decreased to 6.62 per 100 person-year at 12-month interval indicating increased VTE risk in the first 6 months of ICI exposure. Type of ICI, adjuvant chemotherapy or type of cancer was not able to predict VTE risk on multivariate analysis. **Conclusions:** ICI treatment was associated with an increased incidence of VTE in our study cohort with the highest risk among patients on dual ICI followed by ICI + chemotherapy and ICI monotherapy. Future prospective studies are needed to identify risk factors and biomarkers to improve risk stratification and risk-adapted thromboprophylaxis. Research Sponsor: None.

VTE - IRR expressed per 100 person-years and hazard ratio (HR).

	All Patients	Sub Group IA	Sub Group IB	Sub Group IC
6 months pre-ICI (IRR)	9.41	8.0	14.28	11.29
6 months post-ICI (IRR)	11.76	8.0	28.57	14.12
6 months (HR)	1.25	1.0	2.0	1.25
12 months pre-ICI (IRR)	4.63	4.47	5.0	4.88
12 months post-ICI (IRR)	6.62	7.46	10.0	6.49
12 months (HR)	1.43	1.67	2.0	1.33