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COMPARATIVE IMMUNE AND ORGAN-SPECIFIC TOXICITY SIGNALS OF BRENTUXIMAB VEDOTIN VS PD-1 INHIBITORS IN CLASSICAL HODGKIN LYMPHOMA: A FAERS PHARMACOVIGILANCE ANALYSIS

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BACKGROUND

Brentuximab vedotin (BV) and the PD-1 inhibitors pembrolizumab and nivolumab are both central to classical Hodgkin lymphoma (cHL) therapy. After SWOG S1826 and KEYNOTE-204, they are increasingly alternatives to one another rather than sequential options.

Their mechanisms predict different toxicity: payload-driven off-target cytotoxicity for BV versus T-cell–mediated immune-related adverse events for PD-1 blockade.

Head-to-head safety data within cHL are scarce, and pooled-indication pharmacovigilance confounds drug signal with disease and prior therapy.

OBJECTIVE

To compare organ-specific and immune-mediated adverse event reporting profiles of BV versus PD-1 inhibitors within a cHL-restricted FAERS cohort.

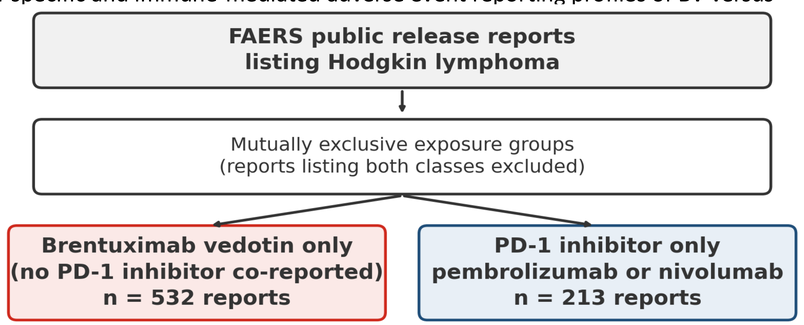

Figure 1. Construction of the mutually exclusive comparison cohorts.

10 prespecified organ-specific event categories compared by ROR

METHODS

Design. Disproportionality analysis of FAERS public release reports listing Hodgkin lymphoma as the reason for use, covering all reports received by FDA from Sept 2011 through May 2026, de-duplicated by case ID.

Groups. Mutually exclusive: BV without a co-reported PD-1 inhibitor (n = 532) versus pembrolizumab or nivolumab without BV (n = 213).

Outcomes. Ten prespecified categories, each a composite of related MedDRA preferred terms.

Analysis. Reporting odds ratios (ROR) with 95% CI, BV as index exposure. ROR >1 favours BV, ROR <1 favours PD-1 inhibitors. Signal = 95% CI excluding 1.0. Reported per READUS-PV.

RESULTS

Eight of ten prespecified categories differed significantly. BV-enriched: Guillain-Barré syndrome, pancreatitis, hepatitis, colitis. PD-1–enriched: thyroiditis, myositis, carditis, pneumonitis. Nephritis and uveitis did not differ.

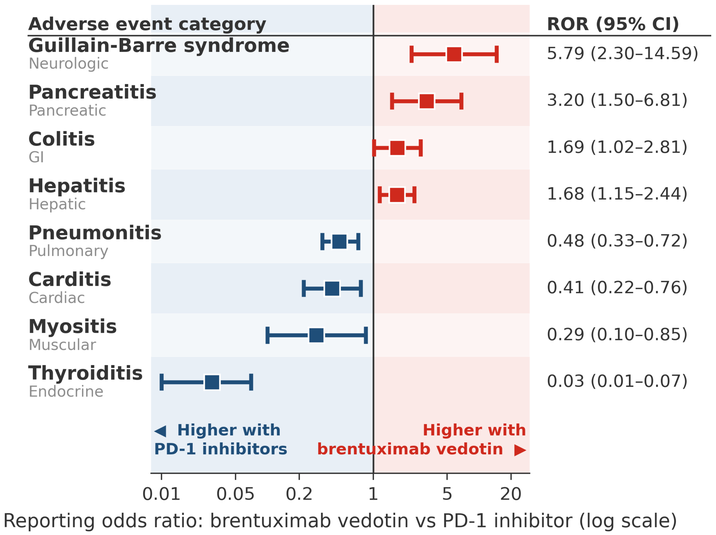

Figure 2. Reporting odds ratios for prespecified adverse event categories, brentuximab vedotin versus PD-1 inhibitors, in Hodgkin lymphoma reports. Squares are point estimates, bars are 95% CIs. Nephritis and uveitis showed no significant difference between classes and are not plotted.

532	213	10	8
BV-only reports	PD-1i-only reports	event categories	significant signals

Adverse event	Organ system	ROR	95% CI	Favours
Guillain-Barré syndrome	Neurologic	**5.79**	2.30–14.59	BV
Pancreatitis	Pancreatic	**3.20**	1.50–6.81	BV
Colitis	Gastrointestinal	**1.69**	1.02–2.81	BV
Hepatitis	Hepatic	**1.68**	1.15–2.44	BV
Pneumonitis	Pulmonary	**0.48**	0.33–0.72	PD-1
Carditis	Cardiac	**0.41**	0.22–0.76	PD-1
Myositis	Muscular	**0.29**	0.10–0.85	PD-1
Thyroiditis	Endocrine	**0.03**	0.01–0.07	PD-1
Nephritis	Renal	NS	CI included 1.0	—
Uveitis	Ocular	NS	CI included 1.0	—

Table 1. RORs are expressed with brentuximab vedotin as the index exposure. “Favours” denotes the class with the higher reporting odds. NS = not significant.

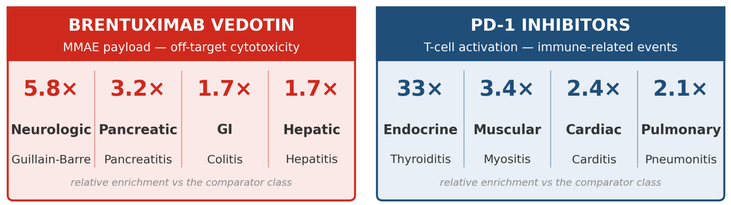

Figure 3. Class-specific toxicity signature; values are relative enrichment versus the comparator class.

CONCLUSIONS

BV and PD-1 inhibitors carry distinct, largely non-overlapping adverse event reporting signatures within cHL.

BV was enriched for neurologic, pancreatic, hepatic and colonic signals, consistent with MMAE payload biology.

PD-1 inhibitors were enriched for pulmonary, cardiac, endocrine and muscular signals, the canonical irAE spectrum. Thyroiditis separated the classes most sharply.

Surveillance should be class-specific: thyroid function and cardiopulmonary symptoms with PD-1 inhibitors, lipase, transaminases and serial neurologic examination with BV.

LIMITATIONS

Spontaneous reporting carries under-reporting, notoriety and channelling bias, and FAERS has no denominator, so RORs reflect relative reporting rather than incidence. Causality cannot be inferred. Residual confounding by line of therapy remains, and no adjustment was made for ten comparisons. Findings are hypothesis-generating.

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REFERENCES