

Open Insurance Claims Database vs Closed Insurance Claims Database to Support Pharmacovigilance Review of Potential Safety Events in Patients With B-Cell Malignancies: A Fit-for-Purpose Evaluation

Poster #44
Publication #1040

Conflict of Interest Statement: All authors disclose employment and stock ownership with BeiGene, Ltd.

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BACKGROUND

- Advances in informatics create a wide variety of real-world data (RWD) sources to facilitate insight generation and support drug development
- The use of RWD sources to support detection of pharmacovigilance (PV) signals and clinical safety review in oncology requires careful consideration due to a higher burden of comorbidity and concomitant medication use in patients with cancer
- Insurance claims data, commonly used in PV settings for safety assessment purposes, are typically classified into 2 categories: closed claims and open claims
- Both closed claims and open claims data have been used in pharmaceutical research.¹ Closed payer claims data are generated directly from payer organizations, while open claims data are sourced from data aggregators within the healthcare system^{2,3}

OBJECTIVES

- To assess and compare the results of safety outcomes analyses in patients with B-cell malignancies, using examples of closed (IBM MarketScan) and open (Symphony Health Solution) claims databases and using the examples of 2 cardiovascular outcomes (atrial fibrillation [AF] and hypertension [HTN])

METHODS

- Design:** This was a cohort study in adult patients with relevant ICD-9 and -10 diagnosis codes for B-cell malignancies between 2015 and 2019 in the IBM MarketScan (closed claims) and Symphony Health Solution (open claims) databases
- Index date:** The index date was defined as the first occurrence of a medical claims record for a B-cell malignancy, including chronic lymphocytic leukemia/small lymphocytic lymphoma, mantle cell lymphoma, marginal zone lymphoma, and Waldenström macroglobulinemia
- Main outcome measures:** The main outcome measures were occurrence of an acute cardiovascular (CV) event (AF) and a chronic CV event (HTN) in patients aged ≥65 years following a cancer diagnosis
- Statistical analysis:** A time-to-event analysis was conducted to estimate the event rate of AF and HTN following the diagnosis of B-cell malignancies in the IBM MarketScan and Symphony Health Solution databases separately. Additionally, the cumulative incidence rate at 1 to 5 years after the index date was estimated for both databases. Patient characteristics, including age and sex, were also described

RESULTS

- A total of 14,592 patients with B-cell malignancies in the IBM MarketScan database and 198,755 patients in the Symphony Health Solution database were included
- Patients with B-cell malignancies were significantly younger (age <65 years, 52.8% vs 27.8%; $P < .0001$; **Table 1**) and had a shorter duration of available follow-up (median duration of 20.4 vs 35.9 months [data not shown]) in the IBM MarketScan database compared with the Symphony Health Solution database, respectively
- In patients aged ≥65 years, the event rate for AF was higher in the IBM MarketScan database vs the Symphony Health Solution database (1.28 vs 0.49 events per 100 person-months, respectively); the cumulative incidence of AF was higher in patients in the IBM MarketScan database compared with the Symphony Health Solution database (eg, 1 year, 20.5% vs 9.7%; 2 year, 25.2% vs 13.3%, respectively; **Table 2**)
- Similarly, among patients aged ≥65 years with HTN, event rates were comparable between the data sets (2.94 vs 2.16 events per 100 person-months); cumulative incidence of HTN was similar between the 2 databases in patients aged ≥65 years (eg, 1 year, 37.4% vs 37.1%; 2 year, 46.9% vs 43.6%; **Table 2**)

Table 1. Baseline Demographics of Patients With B-Cell Malignancies in the IBM MarketScan and Symphony Health Solution Databases

	IBM MarketScan			Symphony Health Solution		
	Overall (N=14,592)	Patients developing AF (n=2078)	Patients developing HTN (n=4953)	Overall (N=198,755)	Patients developing AF (n=25,546)	Patients developing HTN (n=84,618)
Condition, n (%)^a						
CLL/SLL	10,886 (74.6)	1560 (14.3)	3801 (34.9)	155,416 (78.2)	20,596 (13.3)	67,840 (43.7)
MCL	898 (6.2)	147 (16.4)	263 (29.3)	14,484 (7.3)	1816 (12.5)	5501 (38.0)
MZL	1885 (12.9)	225 (11.9)	583 (30.9)	16,676 (8.4)	1554 (9.3)	6603 (39.6)
WM	923 (6.3)	146 (15.8)	306 (33.2)	12,179 (6.1)	1580 (13.0)	4674 (38.4)
Age, years						
Mean (SD)	66.0 (13.26)	75.9 (11.32)	69.7 (12.90)	67.4 (8.30)	70.8 (5.05)	68.6 (6.91)
Median	64.0	78.0	70.0	72.0	72.0	72.0
<65 years, n (%) ^a	7706 (52.8)	424 (5.5)	2024 (26.3)	55,289 (27.8)	2800 (50.6)	18,744 (33.9)
≥65 years, n (%) ^a	6886 (47.2)	1654 (24.0)	2929 (42.5)	143,466 (72.2)	22,746 (15.9)	65,874 (45.9)
Sex, n (%)^a						
Female	6321 (43.3)	758 (12.0)	2070 (32.7)	85,319 (42.9)	9139 (10.7)	36,084 (42.3)
Male	8271 (56.7)	1320 (16.0)	2883 (34.9)	113,419 (57.1)	16,407 (14.5)	48,534 (42.8)

AF, atrial fibrillation; CLL, chronic lymphocytic leukemia; HTN, hypertension; MCL, mantle cell lymphoma; MZL, marginal zone lymphoma; SLL, small lymphocytic lymphoma; WM, Waldenström macroglobulinemia.

^a For the subgroups, the percentages were calculated as proportions of each row's overall population (ie, percentages used each row's overall number as the denominator).

Table 2. Event Proportion and Rates of AF and HTN in Patients Aged ≥65 Years With B-Cell Malignancies

	AF		HTN	
	IBM MarketScan (n=6886)	Symphony Health Solution (n=143,466)	IBM MarketScan (n=6886)	Symphony Health Solution (n=143,466)
Event, n (%)	1654 (24.0)	22,746 (15.9)	2929 (42.5)	65,874 (45.9)
Event rate per 100 person-months (95% CI)	1.28 (1.22-1.34)	0.49 (0.48-0.50)	2.94 (2.84-3.05)	2.16 (2.15-2.18)
Cumulative incidence rate (95% CI), %				
1 year	20.5 (19.5-21.5)	9.7 (9.6-9.9)	37.4 (36.2-38.6)	37.1 (36.9-37.4)
2 year	25.2 (24.1-26.4)	13.3 (13.1-13.5)	46.9 (45.5-48.3)	43.6 (43.4-43.9)
3 year	28.7 (27.4-30.0)	16.3 (16.0-16.5)	53.1 (51.5-54.7)	48.1 (47.8-48.3)
4 year	32.8 (31.1-34.4)	18.8 (18.6-19.1)	57.8 (55.9-59.6)	51.7 (51.4-52.0)
5 year	34.7 (32.6-36.9)	21.1 (20.8-21.4)	60.4 (58.2-62.6)	54.6 (54.2-54.9)

AF, atrial fibrillation; HTN, hypertension.

CONCLUSIONS

- Event rates for HTN, a chronic condition, in older patients were similar in the closed (IBM MarketScan) and open (Symphony Health Solution) insurance claims, but event rates for AF, an acute condition, appeared to be lower in the open claims database
- Despite the benefit of a longer follow-up and larger patient sample size in the open claims database, an acute event such as AF is likely to be under reported
- PV signal reviews using contextual real-world insight from an open claims database may be useful but should be interpreted with caution
- In studies using RWD for PV, it is critical that a database fit-for-purpose assessment is performed to ensure both the relevance and quality of the data for the intended purpose

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ACKNOWLEDGMENTS

This study was funded by BeiGene, Ltd. Editorial assistance was provided by ArticulateScience, LLC, and supported by BeiGene.

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