

Open insurance claims database vs closed insurance claims database to support pharmacovigilance review of potential safety event in patients with B-cell malignancies: a fit for purpose evaluation

Authors: Soraya Azmi¹, Lili Zhou¹, Binglin Yue¹, Nazha M. Diwan¹, Enda Zhu¹, Shicheng Weng¹, and Tzuyung Douglas Kou¹

Affiliations: ¹BeiGene USA, Inc., San Mateo, CA, USA

Background: Advances in informatics create a wide variety of real-world data (RWD) sources to facilitate insight generation to support drug development. The utilization of RWD sources to support pharmacovigilance (PV) signal and clinical safety review in oncology requires careful consideration due to a higher burden of comorbidity and concomitant medication use.

Objectives: To evaluate two cardiovascular outcomes in patients (pts) with B-cell malignancies using two large administrative claims databases: IBM MarketScan and Symphony health solution data.

Methods: Adult pts with relevant diagnosis codes for B-cell malignancies from 2015 in MarketScan (closed insurance claims) and Symphony (open claims) databases were included in the analyses. The index date was defined as the first occurrence of medical claims record for a B-cell malignancy. Pt characteristics at baseline were described. The occurrence of an acute cardiovascular (CV) event (atrial fibrillation [AF]) and a chronic CV event (hypertension [HTN]) among pts aged ≥ 65 at 1 and 2 years after index date were also described.

Results: Of the 14,592 pts in MarketScan and 193,430 pts in Symphony, pts with B-cell malignancies were significantly younger (age < 65 yrs: 52.8% vs 24.4%; $P < 0.0001$) and had a shorter duration of available follow-up (median duration of 20.4 vs 34.9 months) in MarketScan vs Symphony, respectively. In pts aged ≥ 65 , the 1-year and 2-year event proportions for AF were higher among pts in MarketScan vs Symphony (year-1: 20.5% [95% CI: 19.5%, 21.5%] vs 10.9% [95% CI: 10.8%, 11.1%]; year-2: 25.2% [95% CI: 24.1%, 26.4%] vs 14.9% [95% CI: 14.7%, 15.1%], respectively). The event rate (per 100 person-months) for AF was also higher in MarketScan (1.28 [95% CI: 1.22, 1.34]) vs Symphony (0.53 [95% CI: 0.53, 0.54]), respectively. The HTN event proportions at 1-year and 2-year in pts aged ≥ 65 were similar between the two databases. The HTN event rate in MarketScan vs Symphony was 37.4% (95% CI: 36.2%, 38.6%) vs 45.8% (95% CI: 45.6%, 46.1%) at year 1 and 46.9% (95% CI: 45.5%, 48.3%) vs 53.0% (95% CI: 52.7%, 53.2%) at year 2, respectively; event rates per 100 person-months were comparable between the datasets (2.94 [95% CI: 2.84, 3.05] vs 3.10 [95% CI: 3.08, 3.12], respectively).

Conclusion: Event rates of a chronic condition such as HTN in older pts were similar in the two datasets but an acute outcome such as AF appeared to be lower in an open claims database. Despite the benefit of a longer follow-up and larger pt sample size in the open claims database, an acute event such as AF is likely underestimated. PV signal reviews using contextual real-world insight from an open-claims database may be useful but should be interpreted with caution.