A pilot study to evaluate the feasibility of using OHDSI analytical tools for supporting safety surveillance

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OHDSI analytics tools have promising potential for utilising real world data sources to support validation of safety signals.

Key result

- A new-user comparative cohort study was conducted to evaluate the value of implementing population level effect estimation in a RWD setting.
- The application of the OHDSI analytics tools supports a previously validated safety signal of acute cholecystitis following the exposure of liraglutide.

Methods

- An observational new-user cohort was created for target drug exposure (liraglutide), comparator drug exposure (sulfonylureas or SGLT-2 inhibitors), and the outcome of acute cholecystitis defined by the SNOMED code E862F00.
- The study cohorts were created using Truven MarketScan employer based insurance claims data (2). Qualifying target and comparator cohort are shown in Figure 1.

Figure 1: Comparative new user cohort definition

1:3 propensity score (PS) matching was performed including age, gender, parity, body mass index, retinopathy, nephropathy, neuropathy, cardiovascular diseases, and obesity as covariates (Figure 2).

Figure 2: Propensity score distribution before and after the propensity score matching

- 67378 subjects from the target cohort have at least one condition record for acute cholecystitis.
- The prevalence of acute cholecystitis was 2.30 per 1000 subjects for the target drug cohort, and 1.23 per 1000 subjects for the comparator drug cohort.

Figure 3: Survival probability and the hazard ratio

- The minimum detectable relative risk was 1.62 ± 0.17 (SE). The target drug was associated with a higher risk of acute cholecystitis over a median three-month follow-up period (HR 2.26, 95% CI 1.70 – 3.03) (Figure 3).

Next steps will be a new test case for another therapeutic area including negative outcome controls and the data driven selection of covariates.

Key results

- Real world data sources (RWD) can support validation of safety topics especially when the evidence from traditional safety data sources is scarce.
- Acute cholecystitis and acute cholelithiasis are known risks for Victoza® (liraglutide) and Saxenda® (liraglutide) (1).
- A known risk for liraglutide was chosen for the pilot study to evaluate the feasibility of implementing population level effect estimation into the safety surveillance process using the OHDSI analytics tools.

Figure 3: Survival probability and the hazard ratio

- OHDSI analytics tools have promising potential for utilising real world data sources to support validation of safety signals.

Summary

- Application of the OHDSI analytics tools supports a previously validated safety signal of acute cholecystitis following the exposure of liraglutide.

Conclusion

- A new-user comparative cohort study was conducted to evaluate the value of implementing population level effect estimation in a RWD setting.
- Acute cholecystitis and acute cholelithiasis are known risks for liraglutide.
- The application of the OHDSI analytics tools supports a previously validated safety signal of acute cholecystitis following the exposure of liraglutide.

2. 2. IBM® Watson Health™. Commercial Claims and Encounters Database and Medicare Supplemental and Coordination of Benefits Database User Guide. Certain data used in this study were supplied by International Business Machines Corporation. Any analysis, interpretation, or conclusion based on these data is solely that of the authors and not International Business Machines Corporation.