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Performing a Descriptive Study of Diverticulitis and Gastrointestinal Perforations in Patients with Rheumatoid Arthritis Using OHDSI Tools

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Abstract

To generate evidence on the safety profile of drug class exposures in patients with rheumatoid arthritis (RA), a retrospective study design was used to estimate incidence rates of diverticulitis and gastrointestinal perforations (GIP) in patients with RA enrolled in Truven MarketScan Commercial Claims and Encounters (CCAE) and Truven MarketScan Medicare Supplemental Beneficiaries (MDCR) databases, during 2003-2013. The cohorts for identifying people with RA, exposed to various drug classes, experiencing a GIP or diverticulitis were created in the ATLAS tool built on the OHDSI platform. The process involved defining the code list used to identify each cohort with ATLAS, and constructing the CIRCE expression to select the population from the data. Execution of statistics were handled in SQL and packaged as an R module. Overall the incidence rate of diverticulitis among younger patients (<50 years) was approximately 3 cases per 1,000 person-years, with higher incidence around 8-11 cases in patients older than 80 years. The incidence of overall GIP was less than 1 per 1,000 person-years in younger patients and 1-2 cases per 1,000 person-years in older patients. This study generated both clinically and methodologically important results. Use of OHDSI tools enabled efficient, reproducible, and transparent production of study artifacts.

Introduction

Literature on the occurrence of diverticulitis and GIP in patients with RA exposed to different therapies is limited. The objective of this study was to estimate incidence rates of the two outcomes in RA patients using two large US claims databases, while employing the common data model and standardized vocabularies to generate code lists and to identify cohorts that facilitate reproducibility and transparency in scientific research.

Methods:

This descriptive study involved a retrospective cohort design using de-identified data from Truven CCAE and Truven MDCR US claims databases. The two databases were chosen for their capture of younger and older patients, while being largely representative of the insured population in the US. The overall RA study cohort consisted of adults (≥18 years of age on index date) with at least two claims for a diagnosis of RA on separate visits within a 6-month timeframe during the study period, January 1, 2003 – December 31, 2013. In addition, four sub-cohorts were identified based on exposure to drug classes – “any biologics”, “tumor necrosis

factor inhibitor (TNFi) biologics", "non-TNFi biologics" and "biologic-naïve". Patients were followed from a defined index date for each cohort until a specified end date.

Definition of code lists (known as concept sets) and the identification of the study population (using cohort definitions with CIRCE) was enabled by ATLAS, which is a tool built on the OHDSI technology stack. The key component of these cohort definitions was that they were human-readable, machine interpretable and non-ambiguous. For the individual treatment cohorts, custom queries were written (based on the queries produced by CIRCE) to identify drug exposures among people belonging to the RA cohort. Examples of print-friendly forms from ATLAS that were generated for this study will be shown in the poster, and not included here due to space considerations.

Incidence rates (cases per 1,000 person-years of follow-up) stratified by age (<50 and ≥50 years for Truven CCAE and <80 and ≥80 years for Truven MDCR) were computed for diverticulitis and GIP, along with 95% confidence intervals (CI), calculated using the normal approximation for a Poisson rate. The implementation of the incidence rate calculation and CI were handled in SQL, and packaged as an R module. The code is open source and freely available on github.

Results:

The median age of RA patients in Truven CCAE was 53 years and 72 years in Truven MDCR. Overall the age-stratified incidence rate of diverticulitis among younger patients (<50 years) was approximately 3 cases per 1,000 person-years, with higher incidence in older patients, around 8-11 cases observed in patients older than 80 years across the different cohorts. The incidence of overall GIP was less than 1 case per 1,000 person-years in younger patients (<50 years) and 1-2 cases per 1,000 person-years in older patients. When stratified by site of GIP (lower or upper), incidence rates of lower GIP appeared to be numerically higher than incidence of upper GIP in the different age groups. No additional confounder adjustment was performed.

Conclusions:

Medically important results from this study included generation of diverticulitis incidence in RA patients, while incidence of GIP was found to be consistent with the limited data on the topic in the literature. The study also showcased the use of novel OHDSI tools and the common data model platform that aided in generating real world evidence in an efficient, reproducible, and transparent manner. Due to a limitation in cohort definitions, the RA sub-cohorts for drug exposures were manually created based off of the CIRCE-generated cohort definition for RA. The report output also was not produced by OHDSI tools. These features would be a welcome addition to the OHDSI technology stack.