Detailed Cancer Specific Analytics in the Remote OHDSI Network Settings

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Introduction

Observational research in oncology is more challenging than other conditions. Clinically relevant information on disease episode, treatment and outcomes that appropriately reflects patients' journey requires data abstraction and is rarely available in the source data. Currently, the OMOP CDM does not adequately cover cancer diagnoses, treatments and episodes. The OMOP Oncology Module extends the OMOP CDM and Standardized Vocabularies to support the comprehensive representation of cancer conditions, treatments, and disease abstraction required for generation of robust evidence in oncology. In this work, the utility of the Oncology Module to generate real-world evidence in a distributed network was assessed as a part of an ongoing retrospective cohort study of patients with metastatic bladder cancer.

Method

Data from electronic health records (EHR) and cancer registries from Ajou University, IQVIA Oncology Electronic Medical Record (OncoEMR), IQVIA OpenClaims, Memorial Sloan Kettering (MSK) Cancer Center, Tuft University Medical Center, Columbia University Medical Center and Northwestern University were used in this observational retrospective study. Study population consisted of adult patients (>=18 years) with metastatic bladder cancer diagnosis who had no history of other primary malignancies (except for non-melanoma skin cancers) three years prior to diagnosis of bladder cancer and have records available from 01 January 2000 through 30 April 2030. Patients were followed up from date of diagnosis with metastatic bladder cancer to date of death, last encounter in the database or end of study at 30 April 2020, whichever occurred first. Patients' demographics and clinical characteristics were summarized descriptively. Treatment regimens (defined through HemOnc) were inferred from the individual drug exposure using chemotherapy regimen detection algorithm. Distribution of treatment regimens were summarized by line of therapy. Time to first line treatment discontinuation and time to initiation of the second line of therapy were described using Kaplan-Meier (KM) method for all patients and by treatment regimen categories. Index date was set at time of initiation of antineoplastic regimens for all time to event analysis.

Results

All participating sites successfully converted their raw data into the OMOP Oncology representation, combining Tumor Registry and EHR data, and passed quality assurance testing. All analytics were generated centrally, distributed to the institutions and executed locally. Study results were available from six participating centers; Ajou university, OncoEMR and OpenClaims, MSK, Columbia and Tufts university. Results from other participating centers will be incorporated once analyses are completed. Using a standardized cohort definition, a total of 11,525 patients with metastatic bladder cancer were identified in the six participating centers. Median age at the time of first encounter with metastatic bladder cancer was between 52 to 69 years ranging from 18 to 96 years. Between 61% to 74% of patient were male. Median follow up time from diagnosis with metastatic bladder cancer ranged from 340 (155-771) days in OpenClaims to 474 days (234-1,764) days in Ajou. The most common regimens in the first line of therapy was Cisplatin+Gemcitabine in MSK, OncoEMR and OpenClaims (34% MSK, 24% in OncEMR and 24% in OpenClaims) and Gemcitabine monotherapy in Ajou (64%). Distribution of the most common treatment regimens in the first and second of therapy for patients with metastatic bladder cancer is presented in the Figure 1. Median time to first and second line treatment discontinuation

ranged from 44 to 78 days and 40-59, respectively. KM analysis of time to first line treatment discontinuation and time to initiation of the second line for the most common regimens are presented in Figure 2.

Discussion

The overall feasibility of the OMOP Oncology Module to generate real-world evidence in a distributed network was successfully tested. The observed demographics of the patient population across participating sites was similar to the known epidemiology of the disease and distribution of the treatment regimens was in line with clinical guidelines' recommendations. The difference observed in treatment between centers can be due to the existing difference in medical practice and standard of care across the collaborating centers and will be fully explored as a part of the study. The study will incorporate data from other data partners that are in the process of improving the accuracy of the integration of their Tumor Registry data into OMOP.

Figure 1. Distribution of the most treatment regimens in the first and second line of therapy for patients with metastatic bladder cancer in four select network participants
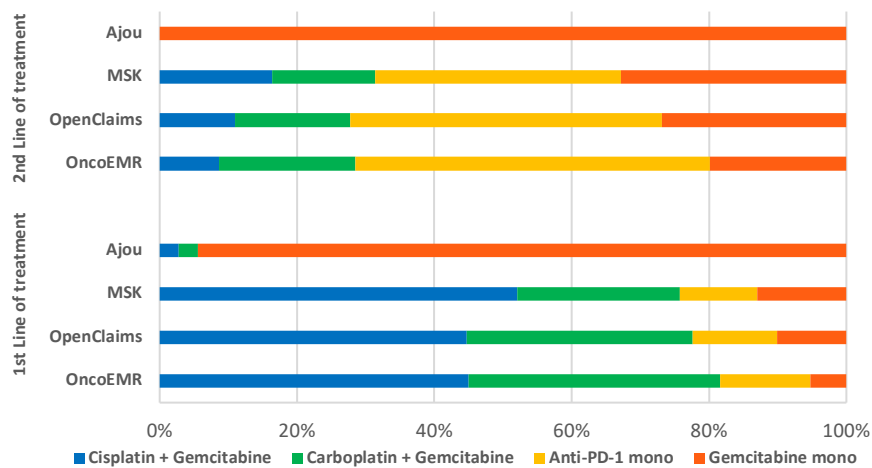
Figure 2. Kaplan-Meier analysis of time to first line treatment discontinuation (TTD) and time to initiation of the second line (TTNT)