Molecular diagnostic classification for cancers of unknown primary (CUP): post-testing diagnosis and treatment impact analysis from real-world claims data

Abstract 6610

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INTRODUCTION

Next-generation sequencing-based molecular diagnostic classifiers can help to identify the site-of-origin and/or histology for patients diagnosed with a cancer of unknown primary (CUP). Improved diagnoses may enable the selection of targeted, site-specific therapies for this vulnerable population with high unmet need who might otherwise be treated with empiric chemotherapy regimens or choose hospice care based on worsening performance status (Figure 1). Though NCCN guidelines do not endorse the use of molecular diagnostic classifiers as standard of care for CUP patients due to limited clinical evidence, subtype identification can unlock additional treatment options for patients. Here, we linked results from a commercial molecular diagnostic classifier with claims data to understand how the use of this test impacted patient care in the real-world setting.

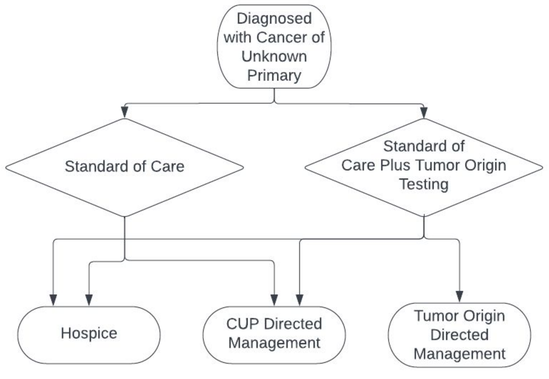

Figure 1. Patients with a CUP diagnosis have historically been restricted to the left-hand side of the diagram. The use of a molecular diagnostic classifier enables a third option depicted on the right-hand side, where patients are provided targeted care based on the histological subtype of their tumor. The use of targeted approaches can be measured through diagnosis code and treatments that align with subtype-specific guidelines

SUMMARY

- Using **real-world claims data**, we show that molecular diagnostic testing utilizing the Tempus TO test—an RNA-based classifier — **led to subtype-aligned diagnosis or medications for 60%** of CUP patients.
- For CUP patients with TO predicted lung adenocarcinomas, **85% had a new subtype-aligned medication claim**, and **78% had subtype-aligned immune checkpoint blockade (ICB) therapy claims**.

METHODS AND RESULTS

We assessed de-identified claims data from the Komodo Healthcare Map (a database including provider visits, laboratory tests, procedures, imaging, and prescriptions) linked to the Tempus multimodal database. Eligible patients received the Tempus Tumor Origin (TO) test (a machine learning classifier that uses RNA-seq data to classify tumors into one of 68 histological subtypes), had pathologist-confirmed CUP and had continuous claims coverage in the 90 days preceding sequencing and for at least 60 days following sequencing. Analyses were limited to patients classified as one of 9 subtypes (each having n>10). Impact was determined by identifying either one or more new diagnostic codes or new subtype-related medication claims following TO testing.

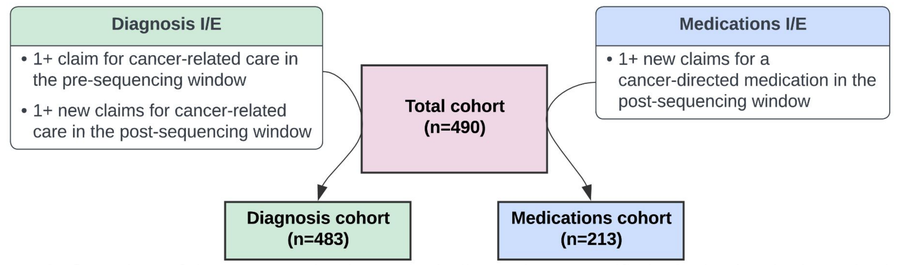

Figure 2. Overview of the assessed cohorts, including cohort-specific inclusion/exclusion criteria.

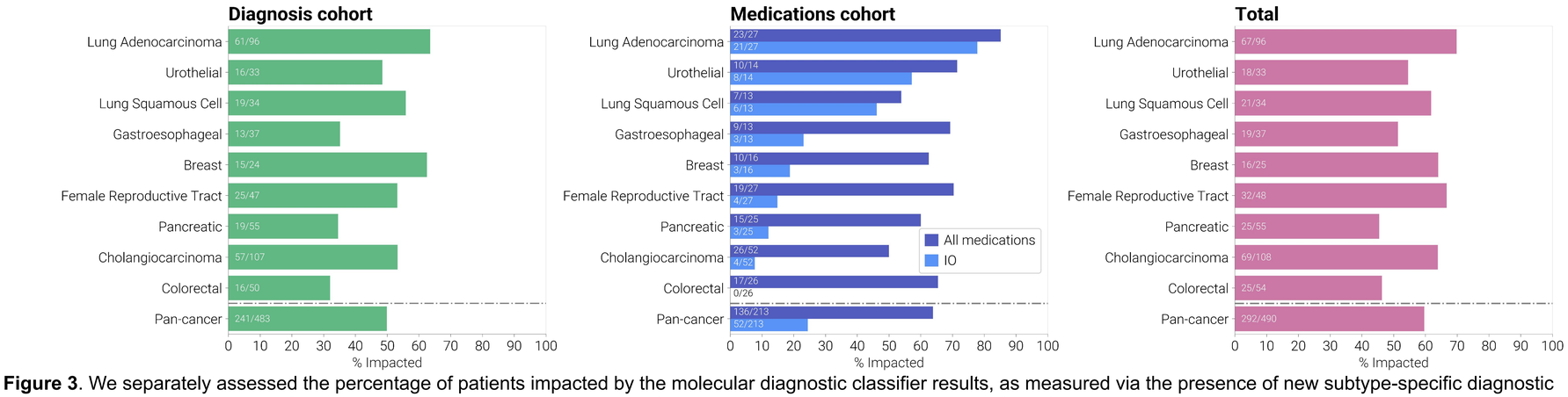

Figure 3. We separately assessed the percentage of patients impacted by the molecular diagnostic classifier results, as measured via the presence of new subtype-specific diagnostic codes (**left**) or new subtype-specific medications (including immunotherapy[IO] as a subset, **center**). The total cohort (**right**) refers to the union of both datasets and impacted here includes patients that met either the diagnosis, medication, or both criteria.