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Validation of an Algorithm to Identify HR+/HER2- Metastatic Breast Cancer in Claims Data

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Introduction

- For therapeutic areas without a specific corresponding International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) code, identification of patient populations can be challenging in administrative claims databases.
- One example is hormone-receptor-positive/human-epidermal-growth-factor-receptor-2-negative (HR+/HER2-) metastatic breast cancer (mBC), the most common breast cancer subtype.
- Validated claims-based definitions are needed to accurately identify HR+/HER2- mBC patients for research studies leveraging claims data.

Objective

- This study aimed to validate an existing claims-based algorithm to identify patients with HR+/HER2- mBC.

Methods

Study Design

- This retrospective cohort study used genomics data from NeoGenomics to validate a claims-based identification algorithm[1-3] in the Komodo Research Dataset (KRD), a database of administrative data and claims capturing routinely collected health services utilization records and expenditures for over 330 million de-identified unique individuals in the US.

Claims-Based Algorithm

- Eligible mBC patients were required to have the following:
  - BC diagnosis codes on at least two medical claims, at least 30 days apart, from January 2016 to August 2023
  - Diagnosis codes for a secondary neoplasm on at least two medical claims, 30 days before or any time after the first BC diagnosis
  - To align with genomics data availability, patients were required to have their mBC diagnosis (i.e., date of first eligible secondary neoplasm claim) on/after January 2020.
- HR+/HER2- status was defined as follows:
  - At least one diagnosis or procedure code for HR+ status, or at least one prescription fill for or administration of HR+ treatment
  - No prescription fills for or administration of treatments indicated for HER2+ BC
- Index date was defined as the first therapy start date after mBC diagnosis.
- Two cohorts were identified:
  - Validation cohort: cases who met the algorithm and had genomics data available before mBC diagnosis
  - Comparison cohort, without genomics data: cases who met the algorithm and did not have genomics data available for validation

Genomics Data Validation

- The validation cohort was then validated against genomics data. Specifically:
  - Immunohistochemistry (IHC) and fluorescence in situ hybridization (FISH) test results prior to mBC diagnosis were used to determine HER2 status.
  - Estrogen receptor (ER)/progesterone receptor (PR) test data were used to determine HR status (positive, negative, or unclear).
  - Patients with unclear results were excluded.

Key Study Variables

- Demographics were evaluated on the index date and reported descriptively for both cohorts; absolute standardized mean difference (SMD) was also reported.
- Overall and subgroup positive predictive values (PPV) and 95% confidence intervals (CI) were calculated for the validation cohort only.

Results

- A total of 143,712 patients met the eligibility criteria.
  - 4,582 patients with appropriate genomics data were included in the validation cohort.
  - The remaining 139,130 patients were included in the comparison cohort.

Figure 1. Cohort Selection Flowchart

Baseline Characteristics (Table 1)

- In the validation cohort, the mean age was 61 years (41% over 64 years) and 49% of patients were White; the majority of patients were commercially insured (44%) or covered by Medicare (41%).
  - Patient characteristics were similar (|SMD|<0.1) between the validation cohort and the comparison cohort, with the exception of geographic region.
  - This difference in region may be because a higher proportion of patients are from the South in the NeoGenomics database compared to the KRD.

HR+/HER2- mBC Algorithm Performance (Table 2)

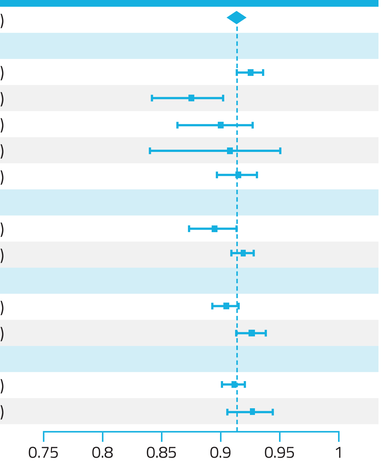
- Genomics data was reviewed for 4,582 patients in the validation cohort.
- PPV of the HR+/HER2- mBC identification algorithm was 91% (95% CI 90–92%).
- The algorithm had higher PPV for patients who were White (93%), ≥65 years (93%), and ≥75 years (93%); and lower PPV among patients who were Black or African American (87%).

Table 1. Baseline Characteristics

	Validation cohort (genomics data available) N=4,582	Comparison cohort (no genomics data available) N=139,130	|SMD|
Age at index (years), mean [median]	61 [62]	62 [62]	0.07
Female, n (%)	4,536 (99.0)	137,034 (98.5)	0.05
Race/ethnicity, n (%)			
White	2,242 (48.9)	66,594 (47.9)	0.02
Black or African American	511 (11.2)	13,557 (9.7)	0.05
Hispanic or Latino	378 (8.2)	11,528 (8.3)	0.00
Asian or Pacific Islander	130 (2.8)	4,441 (3.2)	0.02
Other	145 (3.2)	4,036 (2.9)	0.02
Unknown	1,176 (25.7)	38,974 (28.0)	0.05
Payer channel, n (%)			
Commercial	2,014 (44.0)	58,389 (42.0)	0.04
Medicaid	514 (11.2)	15,758 (11.3)	0.00
Medicare	1,859 (40.6)	58,822 (42.3)	0.03
Unknown	195 (4.3)	6,161 (4.4)	0.01
Geographic region			
Northeast	193 (4.2)	25,428 (18.3)	0.46
Midwest	605 (13.2)	30,956 (22.2)	0.24
South	2,846 (62.1)	53,699 (38.6)	0.48
West	937 (20.4)	28,230 (20.3)	0.00
Unknown	1 (0.0)	817 (0.6)	0.10

Table 2. Positive Predictive Value

Subgroup	PPV (95% CI)
Overall	0.91 (0.90, 0.92)
Race/ethnicity	
White	0.93 (0.91, 0.94)
Black or African American	0.87 (0.84, 0.90)
Hispanic or Latino	0.90 (0.86, 0.93)
Asian or Pacific Islander	0.91 (0.84, 0.95)
Unknown	0.91 (0.90, 0.93)
Age (<50 vs. ≥50)	
<50	0.89 (0.87, 0.91)
≥50	0.92 (0.91, 0.93)
Age (<65 vs. ≥65)	
<65	0.90 (0.89, 0.92)
≥65	0.93 (0.91, 0.94)
Age (<75 vs. ≥75)	
<75	0.91 (0.90, 0.92)
≥75	0.93 (0.91, 0.94)



Conclusion

- The results demonstrate that the claims-based identification algorithm was highly accurate for identifying HR+/HER2- mBC patients, and generalizable to claims data with or without linked genomics data.

References

1. Swallow E, et al. Curr Med Res Opin. 2014; 30(8):1537-45.
2. Guerin A, et al. Expert Opin Pharmacother. 2016; 17(9):1189-96.
3. Li N, et al. J Med Econ. 2016; 19(4):414-23.

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