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Early Adoption of Molecular Residual Disease Testing in Breast Cancer Patients using Real World Data

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Background

- Molecular residual disease (MRD) testing using circulating tumor DNA (ctDNA) as a biomarker is an emerging practice that holds significant promise for improving outcomes for patients with cancer[1].
- MRD testing is minimally invasive and can be used to monitor response to therapy in the neoadjuvant or adjuvant setting and to monitor for cancer recurrence in the surveillance setting[1-3].
- The ctDNA biomarker provides information on responses to neoadjuvant therapy, molecular relapse during surveillance, or indications of response to therapy in the metastatic setting[2-7].
- Hence, MRD testing could provide opportunities for earlier detection and timely intervention, inform the need for imaging, mitigating the risk of disease progression and potentially improving long-term clinical outcomes for patients[2-7].
- Further, prior studies have demonstrated that MRD testing can detect recurrence at least 1 year earlier than radiological imaging[1-3].

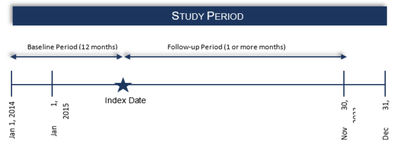
Study Aim

- This study aims to assess the early adoption of MRD testing for patients diagnosed with breast cancer (BC) using real-world claims database (RWD).

Methods and Materials

- A national multi-payer medical and pharmacy claims data (STATinMED RWD Insights) with nearly 80% of the US healthcare system was used.
- Data were extracted for female patients aged ≥18 years between January 1, 2015, and November 30, 2023 (**Figure 1**).
- Index date was defined as the first date of BC diagnosis (**Figure 1**).
- Eligible patients were required to have 1) continuous enrollment for a minimum of 12 months prior to the index date (baseline period), 2) at least 30 days post-index date and, 3) had ≥2 inpatient or outpatient BC claims (ICD-9-CM: 174x, 175x; ICD-10-CM: C50x) (**Figure 1**).
- Patients were excluded if they had other cancers (not including non-melanoma skin cancers), any BC treatment before index, or evidence of pregnancy during the study period.
- BC subtypes were inferred based on the treatment regimens administered, serving as proxies in the absence of direct subtype data.
- Patients' BC metastasis status were defined based on ICD-9 and ICD-10 diagnosis codes on their index date.
- Postmenopausal status was defined as patients aged ≥55 years at index or, those who had a code for bilateral oophorectomy during the baseline period. Otherwise, patients were categorized as premenopausal.
- MRD utilization was tracked from the index date to study completion and/or patient death (**Figure 1**).

Figure 1. Study Design



Note: *The index date was defined as the earliest claim date used to identify the breast cancer patient during the identification period, based on inclusion and exclusion criteria.*

Results

Figure 2. MRD Utilization Patterns

- Among 652,463 eligible patients (mean age: 65.4 years), 815 (0.12%) adopted MRD testing and satisfied inclusion/exclusion criteria
- Of the 815 patients who used an MRD test, the first MRD test was in 2021, increased in 2022 (n=66), then increased substantially in 2023 (n=748)

Table 1. Patient Characteristics

- The mean age of MRD tested patients was 62.7 years, with >50% over 50 years of age
- Over 55% of patients were from the South
- Over 50% of patients received Medicare (51.4%) and over 98% were residing in urban areas
- Most of the patients were white (67.7%) and non-Hispanic (60.1%)
- 36.0% had a college education; over 50% had a household income below $50,000.

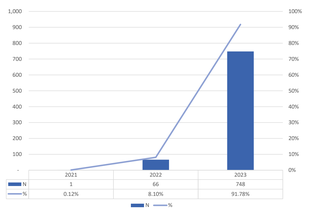


Figure 2. MRD Utilization Patterns 2021-2023

Table 1. Patient Characteristics

	N/ Mean	%/ SD[a]
All Patients (N, %)	815	100%
Age (Mean, SD)	62.68	11.55%
Age Group (N, %)		
18-39	31	3.80%
40-49	82	10.06%
50-64	287	35.21%
65-74	299	36.69%
≥75	116	14.23%
Sex (N, %)		
Male	-	0.00%
Female	815	100%
Geographic Region (N, %)		
Northeast	48	5.89%
North central	127	15.58%
South	452	55.46%
West	188	23.07%
Unknown/Missing	-	0.00%
Payer Channel (N, %)		
Commercial	258	31.66%
Medicare	419	51.41%
Medicaid	138	16.93%
Other[b]	-	0.00%
Urbanicity (N, %)		
Rural	16	1.96%
Urban	799	98.04%
Unknown/Missing	-	0.00%
Patient-reported Race (N, %)		
White	552	67.73%
Black	80	9.82%
Asian	15	1.84%
Other[c]	1	0.12%
Unknown/Missing	167	20.49%
Patient-reported Ethnicity (N, %)		
Hispanic	96	11.78%
Non-Hispanic	490	60.12%
Unknown/Missing	229	28.10%
Patient-reported Education (N, %)		
Less than High School	3	0.37%
High School/Equivalent	284	34.85%
College graduate	184	22.58%
Post-Graduate	109	13.37%
Unknown/Missing	235	28.83%
Patient-reported Household Income (N, %)		
<=$25,000	223	27.36%
$25,001 - $50,000	188	23.07%
$50,001 - $75,000	49	6.01%
$75,001 - $100,000	75	9.20%
>$100,000	60	7.36%
Unknown/Missing	220	26.99%

Table 2. Patient Clinical Information

	N/ Mean	%/ SD
Quan Charlson Comorbidity Index (CCI) (Mean, SD)	0.88	1.7
Quan Charlson Comorbidity Index (CCI) (N, %)		
0	553	67.85%
1	83	10.18%
2	65	7.98%
≥3	114	13.99%
CCI Comorbidities (N, %)		
Myocardial infarction (MI)	17	2.09%
Congestive heart failure (CHF)	28	3.44%
Peripheral vascular disease (PVD)	35	4.29%
Cerebrovascular disease (CBVD)	32	3.93%
Dementia	5	0.61%
Chronic obstructive pulmonary disease (COPD)	80	9.82%
Rheumatologic disease	21	2.58%
Peptic ulcer disease	4	0.49%
Hemiplegia or paraplegia	4	0.49%
Renal disease	28	3.44%
Diabetes without complications	119	14.60%
Diabetes with complications	59	7.24%
Any malignancy	-	0.00%
Metastatic solid tumor	16	1.96%
Mild liver disease	21	2.58%
Moderate/severe liver disease	1	0.12%
Acquired immunodeficiency syndrome (AIDS)	1	0.12%
Individual Comorbidities (N, %)		
Cardiac disease	336	41.23%
COPD/Asthma	99	12.15%
Diabetes	125	15.34%
Liver disease	21	2.58%
Lung disease	98	12.02%
Inflammatory diseases	4	0.49%
Hypertension	284	34.85%
Osteoporosis	52	6.38%
Obesity	72	8.83%
Depression and anxiety	148	18.16%
Thyroid disorder	141	17.30%
Breast cancer type (N, %)		
HR+HER2-	531	65.15%
Triple negative	190	23.31%
HR+HER2+	77	9.45%
HR-HER2+	17	2.09%
Non-Metastatic (N, %)		
HR+HER2-	483	59.26%
HR-HER2- (Triple negative)	176	21.60%
HR+HER2+	65	7.98%
HR-HER2+	15	1.84%
Metastatic (N, %)		
HR+HER2-	48	5.89%
HR-HER2- (Triple negative)	14	1.72%
HR+HER2+	12	1.47%
HR-HER2+	2	0.25%
Menopausal status (N, %)		
pre	189	23.19%
post	626	76.81%

Table 2. Patient Clinical Information

- The average Charlson Comorbidity index (CCI) was 0.88 (±1.7)
- Patients presented with a wide range of comorbid conditions
- 65.2% of patients had HR+/HER2-, 23.3% had TNBC, 9.5% had HR+/HER2+ and, 2.1% had HR-/HER2+.
- Over 90% of patients had non-metastatic disease
- Almost 77% patients were postmenopausal

Table 3. MRD Test Frequency and Timing Patterns Among Patients Undergoing MRD Testing (N=815)

- The mean follow-up time per patient was 38.76 months (±26.57)
- The median follow-up per patient of 29.70 months.
- The mean number of MRD tests per patient was 1.72 (±1.27)
- During the study time frame, 60.9% of patients received only one MRD test, 23.1% received two, 8.3% received three and the remaining 7.7% of patients received 4 or more MRD tests, for up to 10 MRD tests.

Table 4. Timing between MRD Tests (n=319, 39.14%)

- For all BC subtypes,
  - The average time between the 1st and 2nd MRD tests was at least 85 days, longer for HR-/HER2+, it was 94.3 days.
  - The average time between 2nd and 3rd MRD test was at least 70 days, much longer for HR-/HER2+, it was 102 days
  - The average interval between tests decreased with additional MRD testing, as did the number of patients undergoing MRD tests.

Table 3: MRD Test Frequency and Timing Patterns Among Patients Undergoing MRD Testing (N=815)

	N/Mean	%/SD
Patient Follow Up (Months)		
Mean	38.76	26.57
Median (Q1, Q3)	29.70	(18.15, 55.59)
Testing Descriptive Statistics		
Mean	1.72	1.27
Median	1	
Min	1	
Max	10	
Patient test distribution (N=815)	**N**	**%**
1	496	60.86%
2	188	23.07%
3	68	8.34%
4	31	3.80%
5	13	1.60%
6	8	0.98%
7	3	0.37%
8	4	0.49%
9	2	0.25%
10	2	0.25%

Table 4. Timing Between MRD Tests Among Patients with Multiple Tests (N = 319)

	Mean	SD
HR+/HER2- (N = 187)		
Average number of days between test 1 and test 2 (N= 187)	89.34	49.75
Average number of days between test 2 and test 3 (N=75)	70.71	40.31
Average number of days between test 3 and test 4 (N= 38)	59.89	33.88
Average number of days between test 4 and test 5 (N=22)	48.45	25.90
Average number of days between test 5 and test 6 (N=13)	34.77	19.83
HR-/HER2- (Triple negative) (N = 85)		
Average number of days between test 1 and test 2 (N=85)	87.49	44.39
Average number of days between test 2 and test 3 (N=34)	79.50	39.84
Average number of days between test 3 and test 4 (N=14)	67.50	40.45
Average number of days between test 4 and test 5 (N=5)	39.80	10.33
Average number of days between test 5 and test 6 (N=4)	44.00	14.02
HR+/HER2+ (N = 37)		
Average number of days between test 1 and test 2 (N=37)	85.54	50.11
Average number of days between test 2 and test 3 (N=18)	72.89	42.49
Average number of days between test 3 and test 4 (N=8)	76.88	38.23
Average number of days between test 4 and test 5 (N=4)	43.50	10.66
Average number of days between test 5 and test 6 (N=2)	68.50	28.99
HR-/HER2+ (N = 10)		
Average number of days between test 1 and test 2 (N=10)	94.30	47.84
Average number of days between test 2 and test 3 (N=4)	102.00	47.78
Average number of days between test 3 and test 4 (N=3)	41.67	13.32
Average number of days between test 4 and test 5 (N=1)	92.00	N/A
Average number of days between test 5 and test 6 (N= 0)	N/A	N/A

Conclusions

- Using the RWD, this study provides insights into the early adoption of MRD testing among BC patients in the United States.
- Findings demonstrated an upward trajectory in MRD testing adoption over the study period.
- Heterogeneity and variations were observed in early utilization and adoption patterns of MRD in the real-world setting.
- This study is subject to the characteristics and limitations associated with claims database.
- Further investigation with augmented time frame is warranted to evaluate MRD utilization in breast cancer over time.
- Findings herein provide hypothesis generating opportunities for future evidence generation.

Disclosure:
This study is funded by Exact Sciences. The presentation is the intellectual property of the author/presenter. Contact Ning Yan Gu, PhD, ngu@exactsciences.com, for permission to reprint and/or distribute

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