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Survival Outcomes in Metastatic Breast Cancer: An analysis of the US population-based SEER database

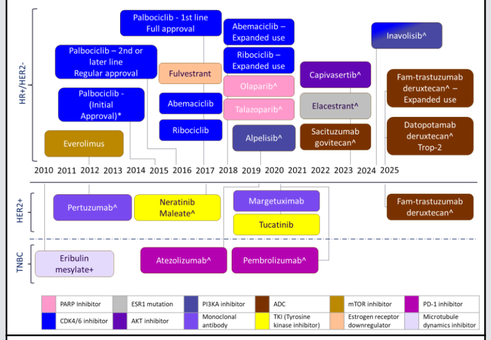
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Background and Objective

- Breast Cancer is the second most common cancer among women in the United States.[1]
- Over the last 15 years, several therapies have been approved for the treatment of metastatic breast cancer (mBC) in the United States (U.S.) (**Figure 1**)
- Given the evolving treatment landscape, it is important to assess and understand overall survival (OS) and related predictors in the real-world setting.
- The objective of this study was to assess OS and breast cancer-specific survival (BCSS) among patients with mBC, and to examine trends in 5-year relative survival over time.

Figure 1. FDA Drug Approvals for Metastatic Breast Cancer from 2010 to 2025



ADC=antibody–drug conjugate; CDK4/6=Cyclin-Dependent Kinase 4 and 6; ESR1=Estrogen Receptor 1; HR+/HER2-=Hormone Receptor–Positive, HER2-negative; mTOR=mammalian Target of Rapamycin; PARP=Poly(ADP-ribose) polymerase; PD-1=Programmed cell Death protein-1; PI3KA= Phosphatidylinositol 3-kinase, alpha isoform; TNBC=Triple-Negative Breast Cancer
^ - Biomarker targeted therapy

Materials and Methods

Study Design

- Non-interventional retrospective cohort study design

Data Source

- Data was obtained from Surveillance, Epidemiology, and End Results (SEER) in the United States.[2]
- SEER collects cancer incidence and survival data from population-based cancer registries, that routinely collect data on patient demographics, tumor characteristics, and follow-up for vital status (survival).
- These data are collected from 22 US geographic areas which covers approximately 48% of the U.S. population.
- Data accessible to researchers via the SEER website link.[2]
- All data are de-identified

Patient inclusion criteria

- Patients of age ≥ 18 years at diagnosis
- Primary diagnosis of breast cancer between 2010 and 2021 (ICD10 code: C50.0 to C50.9)
- Distant (metastatic) Stage as per SEER staging

Patient Exclusion Criteria

- Breast cancer not listed as the primary tumor
- Stage information missing
- No follow up data post diagnosis
- Uncertain/ invalid date at diagnosis

Materials and Methods (cont'd)

Statistical Analyses

- Descriptive statistics were reported for patient demographics and clinical characteristics by breast cancer subtype.
- Survival (OS and BCSS) was estimated using Kaplan–Meier methods for the overall cohort and stratified by age (< 65 years and ≥ 65 years) and by breast cancer subtypes: HR+/HER2-, HER2+ (HR+/HER2+, HR-/HER2+), and triple negative breast cancer (TNBC).
- Survival (OS and BCSS) was estimated from the time of diagnosis to time of death or last date of follow up.
- Breast Cancer specific vs death due to any cause was determined by combining 'SEER cause-specific death' classification and 'SEER other cause of death' classification variables.
- Patients were censored at last follow up, if death not reported.
- Median survival and 5-year survival rates were estimated.
- 5-year relative survival was estimated. Relative cancer survival is defined as the ratio of the observed all-cause survival in a group of individuals with cancer to the expected all-cause survival of a similar group of individuals who do not have cancer.
- Predictors of survival were assessed using multivariate Cox proportional hazards modeling adjusting for confounding factors.

Results

- The cohort included 37,017 patients with mBC. (**Table 1A**)
  - The majority (58%) were aged <65 years, with a mean age of 61 years. 54% of the patients had liver or lung metastases.
  - Prior surgery was reported for 25% of the patients. Among patients with subtypes reported (n=31,656), the proportion of patients with HR+/HER2-, HER2+ (HR+/HER2+, HR-/HER2+), and TNBC subtypes were 60%, 26%, and 14% respectively. (**Table 1B**)

Table 1A. Patient Demographics

Patient Characteristic	Category	Overall (N=37,017) n (%)	HR+/HER2- (N= 18,916) n (%)	HER2+ (N=8,226) n (%)	TNBC (N=4,514) n (%)
Age Group	<65 years	21,312 (58%)	10,577 (56%)	5,684 (69%)	2,816 (62%)
	≥65 years	15,705 (42%)	8,339 (44%)	2,542 (31%)	1,698 (38%)
Gender	Male	448 (1%)	284 (2%)	68 (1%)	28 (1%)
	Female	36,569 (99%)	18,632 (98%)	8,158 (99%)	4,486 (99%)
Race / Ethnicity	African American	5,906 (16%)	2,655 (14%)	1,306 (16%)	1,109 (25%)
	Caucasian	27,414 (74%)	14,358 (76%)	5,924 (72%)	3,032 (67%)
	Asian or Pacific Islander	3,183 (9%)	1,639 (9%)	891 (11%)	310 (7%)
	American Indian/ Alaska Native	284 (1%)	152 (1%)	61 (1%)	35 (1%)
	Unknown	230 (1%)	112 (1%)	44 (1%)	28 (1%)

Table 1B. Patient Clinical Characteristics

Characteristic	Category	Overall (N=37,017) n (%)	HR+/HER2- (N= 18,916) n (%)	HER2+ (N=8,226) n (%)	TNBC (N=4,514) n (%)
Histology	Ductal and lobular	30,641 (83%)	16,944 (90%)	7,565 (92%)	3,855 (85%)
	Epithelial	2,437 (7%)	772 (4%)	263 (3%)	264 (6%)
	Adenocarcinoma	2,190 (6%)	887 (5%)	302 (4%)	228 (5%)
	Other	606 (2%)	238 (1%)	67 (1%)	149 (3%)
	Unspecified	1,143 (3%)	75 (0%)	29 (0%)	18 (0%)
Prior surgery	Yes	9,139 (25%)	4,581 (24%)	2,490 (30%)	1,528 (34%)
	No	27,878 (75%)	14,335 (76%)	5,736 (70%)	2,986 (66%)
Site of Metastasis	Bone	23,470 (63%)	13,754 (73%)	4,659 (57%)	1,848 (41%)
	Brain	2,613 (7%)	989 (5%)	729 (9%)	475 (11%)
	Liver	9,149 (25%)	3,460 (18%)	3,081 (37%)	1,138 (25%)
	Lung	10,941 (30%)	5,011 (26%)	2,471 (30%)	1,656 (37%)
Year of Diagnosis	2010	2,686 (7%)	1,282 (7%)	531 (6%)	332 (7%)
	2011	2,777 (8%)	1,401 (7%)	580 (7%)	323 (7%)
	2012	2,760 (7%)	1,365 (7%)	636 (8%)	316 (7%)
	2013	2,973 (8%)	1,489 (8%)	659 (8%)	351 (8%)
	2014	2,976 (8%)	1,484 (8%)	712 (9%)	340 (8%)
	2015	2,944 (8%)	1,449 (8%)	723 (9%)	348 (8%)
	2016	3,135 (8%)	1,545 (8%)	751 (9%)	360 (8%)
	2017	3,200 (9%)	1,655 (9%)	734 (9%)	364 (8%)
	2018	3,284 (9%)	1,779 (9%)	689 (8%)	445 (10%)
	2019	3,339 (9%)	1,809 (10%)	710 (9%)	432 (10%)
	2020	3,341(9%)	1,788 (9%)	714 (9%)	416 (9%)
	2021	3,602 (10%)	1,870 (10%)	787 (10%)	487 (11%)

- In the overall mBC cohort, median OS was 28 months, with a 5-year OS rate of 28% (Fig 2a, Fig 4) and median BCSS was 32 months, with a 5-year CSS rate of 32% (**Figure 3a, Figure 4**).
- Among patients aged ≥65 years in the overall mBC cohort, median OS and BCSS were 18 and 23 months, respectively, with 5-year survival rates of 20% and 26%.(**Figure 2c, Figure 3c and Figure 4**)

Figure 2. Overall Survival (OS) by Breast Cancer Subtype and Age Group (<65 and ≥ 65 years)

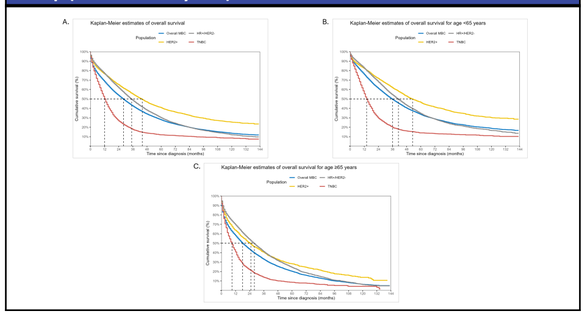
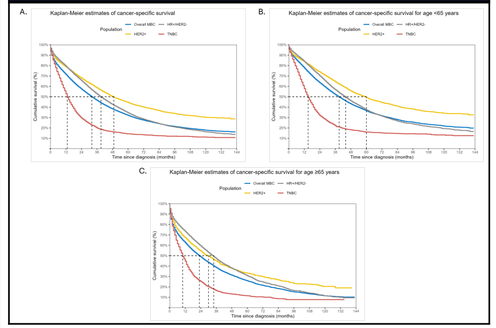
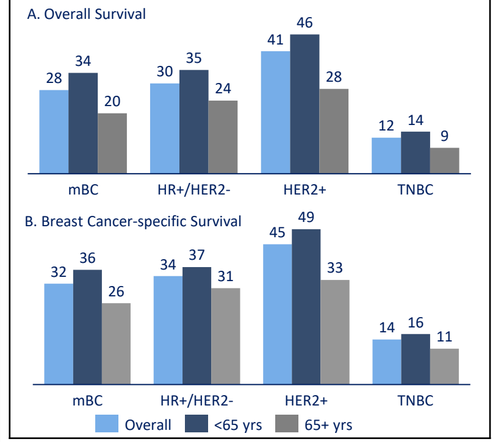


Figure 3. Breast Cancer Specific Survival (BCSS) Stratified By Subtype and Age Group (<65 and ≥ 65 years)



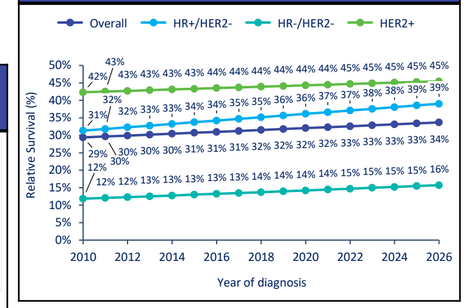
- In the HR+/HER2- mBC subgroup, median OS and BCSS were 35 and 39 months, with a 5-year OS rate of 30% and 34% respectively.(**Figure 2a, Figure 3a, Figure 4**)
- In the HER2+ mBC subgroup, median OS and BCSS were 44 and 49 months, with a 5-year OS rate of 41% and 44% respectively. (**Figure 2a, Figure 3a, Figure 4**)
- In the triple negative mBC subgroup, median OS and BCSS were 12 and 13 months, with a 5-year OS rate of 12% and 14% respectively. (**Figure 2a, Figure 3a, Figure 4**)

Figure 4. Five-year OS and BCSS (%) in Overall mBC and Breast Subtypes



- Five-year relative survival improved from 29% in 2010 to 31% in 2015 and 32% in 2021 for overall mBC with a greater numerical increase observed in HR+HER2- compared to TNBC. (**Figure 5**)

Figure 5. Five-year Relative Survival Trends in Overall mBC and Breast Subtypes



- Significant predictors of OS and BCSS included age, race, histology, breast cancer subtype and prior surgery status (p < 0.05). Overall survival prognosis was significantly (p<0.001) worse for TNBC compared to HR+/HER2- mBC patients (HR;95% CI:2.38;2.29,2.48). (**Table 2**)

Table 2. Cox Proportional Hazards Model Results

Variable	Category	Overall Survival (OS) HR (95% CI)	Breast Cancer Specific Survival (CSS) HR (95% CI)
Age (years)	<65	1.00	1.00
	≥65	1.45 (1.41 - 1.49)**	1.33 (1.29 - 1.37)**
Gender	Female	1.00	1.00
	Male	1.11 (0.97 - 1.26)	1.12 (0.97 - 1.29)
Race	Caucasian	1.00	1.00
	African American	1.29 (1.24 - 1.34)**	1.26 (1.21 - 1.31)**
	Other	0.94 (0.89 - 0.99) *	0.92 (0.87 - 0.98) *
Histology	Ductal/Lobular	1.00	1.00
	Adenocarcinoma	1.15 (1.08 - 1.23)**	1.15 (1.08 - 1.23)**
	Epithelial	1.26 (1.18 - 1.34)**	1.26 (1.18 - 1.35)**
	Other	1.12 (1.00 - 1.25) *	1.07 (0.95 - 1.21)
Prior surgery	Yes	1.00	1.00
	No	2 (1.93 - 2.07)**	2.02 (1.95 - 2.09)**
mBC Subtype	HR+/HER2-	1.00	1.00
	HER2+	0.88 (0.85 - 0.91)**	0.88 (0.85 - 0.92)**
	TNBC	2.38 (2.29 - 2.48)**	2.48 (2.38 - 2.59)**

*p<0.05; ** p<0.001

Limitations

- Detailed information on treatment and related dosing is not available within SEER.
- Observed survival trends might not reflect recently approved treatments for metastatic breast cancer.

Conclusions

- Overall survival in patients diagnosed with mBC between 2010 to 2021 varied by breast cancer subtype, with prognoses relatively worse in TNBC patients compared to HR+/HER2- patients and prognoses relatively better in HER2+ patients compared to HR+/HER2- patients.
- Trends in improvement in relative survival from 2010 to 2021 in the 3 mBC subtypes seem to correspond to the trends in regulatory approvals of drugs for the respective mBC subtypes.
- Continued development of novel therapies for TNBC patients will be key to achieving further improvements in survival outcomes in mBC.

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