HHS Public Access

Author manuscript

Cancer Epidemiol Biomarkers Prev. Author manuscript; available in PMC 2018 June 01.

Published in final edited form as:

Cancer Epidemiol Biomarkers Prev. 2017 June ; 26(6): 809–815. doi:10.1158/1055-9965.EPI-16-0889.

Estimation of the Number of Women Living with Metastatic Breast Cancer in the United States

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Abstract

Background—Distant metastatic breast cancer (MBC), including metastases found at diagnosis (*de novo*) and those occurring later (recurrence), represents the most severe form of the disease, when resource utilization is most intensive. Yet, the number of women living with MBC in the US is unknown. The objective of this paper is to use population-based data to estimate the prevalence of MBC.

Methods—We used a back-calculation method to estimate MBC prevalence from US BC mortality and survival from the Surveillance, Epidemiology and End Results (SEER) registries. Based on the illness-death process, this method assumes that each observed BC death is the result of MBC, either *de novo* or a recurrence with metastatic disease.

Results—We estimate that by January 1, 2017 there will be 154,794 women living with MBC in the United States, 3 in 4 initially diagnosed with stage I–III BC who later progressed to MBC.

Median survival and 5-year relative survival for *de novo* MBC increased over the years, especially in younger women. We estimate a 2-fold increase in 5-year relative survival from 18% to 36%, for women diagnosed with *de novo* MBC at age 15–49 between 1992–1994 and 2005–2012, respectively.

Conclusion—This study demonstrates an increasing number of women in the US living with MBC, likely the result of improvements in treatment and aging of the US population.

Impact—The increasing burden of MBC highlights the importance of documenting recurrence in order to foster more research into the specific needs of this understudied population.

Keywords

Metastasis; Recurrence; Breast Cancer; Prevalence; Backcalculation

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In 2016, there are approximately 3.5 million women living with a history of breast cancer (BC) in the United States(1). This number includes newly diagnosed women with BC undergoing surgery and adjuvant treatment, long term survivors who may be cured of the disease, and women who have experienced a recurrence after a disease free interval. Distant metastatic cancers, including metastases found at diagnosis (*de novo*) and those occurring later in the disease course (distant recurrence), who represent the majority of cases, constitute the most advanced form of the disease. Many groups, including the Orphan Drug Program of the Food and Drug Administration (FDA), health services researchers and especially the cancer survivorship and advocacy community are increasingly interested in assessing the prevalence of women with metastatic breast cancer (MBC) as these women have significant health care needs when resource utilization tends to be continuous and intensive(2–6).

The prevalence of women initially diagnosed with MBC can be directly estimated (7) using population-based cancer registry data on *de novo* MBC and vital-status at the study cut-off date. However, estimating prevalence of those diagnosed with early stage BC who later have had a distant recurrence is challenging, since there are no nationally representative data that capture recurrence. Currently, registries in the US do not routinely collect or report recurrence data.

In the absence of empirical data on the incidence of recurrent MBC, a back-calculation method, Mortality Incidence Approach MODel (MIAMOD) (8, 9), has been used to reconstruct prevalence of recurrent cancer in Australia (10). This method calculates the incidence of MBC (*de novo* and distant recurrence) based on BC mortality and MBC survival. The method has also been used to estimate the prevalence of BC survivors in states within the US (11) when cancer incidence data is not available over the long term.

The objective of this paper is to use national data on BC mortality and MBC survival from Surveillance, Epidemiology and End Results (SEER) registries to estimate the prevalence of women living with MBC in the U.S., including both women initially diagnosed with MBC and those who have progressed to distant MBC. We also calculate separately the prevalence of women diagnosed with *de novo* MBC in SEER and the US (7). The SEER *de novo* MBC prevalence is compared with an estimate based on the backcalculation method to validate the method and calibrate survival (11).

Materials and Methods

Data sources and Definitions

The Surveillance Epidemiology and End Results (SEER) Program collects clinical, demographic, and vital status information on all cancer cases diagnosed in defined geographic areas. Data included in this report are from the SEER-9 and SEER-11 registries (November 2015 Submission) obtained using SEER*Stat software version 8.3.2 (www.seer.cancer.gov/seerstat). SEER-9 covers approximately 11% of the US population and includes: Atlanta, Connecticut, Detroit, Hawaii, Iowa, New Mexico, San Francisco-Oakland, Seattle-Puget Sound, and Utah. For survival analyses we used data from 1992–

2012 from the SEER-11 registries which includes, SEER-9, Los Angeles and San-Jose Monterey. We only included malignant BCs.

Stage at diagnosis was defined using adjusted American Joint Committee on Cancer (AJCC) 6th edition staging classification (12). This stage definition uses extent of disease information for cases diagnosed in 1988–2003 and collaborative staging for cases diagnosed in 2004–2012. *De novo* MBC was defined as AJCC 6 stage IV which includes only tumors with distant metastasis. Stage IV from previous AJCC editions and distant stage from SEER historical summary staging classification include some locally advanced tumors without distant metastasis, e.g., tumors with positive supraclavicular lymph node involvement without distant metastasis. Recurrent MBC was used to designate women initially diagnosed with AJCC stages I–III BC, whose disease later progressed (metastasized) after treatment to distant organs or tissues.

Main inputs to the back-calculation methods are cancer deaths, all cause-deaths, population sizes and MBC survival. We obtained US female deaths due to BC and all causes, from 1990 to 2012 from the National Center for Health Statistics (NCHS) and US female populations from 1990 to 2020 from the US Census Bureau. The population projections are based on the July 1, 2013 population estimates, which are based on the 2010 Census, and provide projections of the population for 2014 through 2060, (https://www.census.gov/population/projections/data/national/2014.html). Deaths and populations were obtained by single calendar year and single age (0–99) using the SEER*Stat software.

Survival associated with cancer diagnosis was assessed via relative survival calculated using SEER*Stat. Relative survival is based on the ratio of overall survival (all causes of death) among cancer cases to the expected survival in individuals without cancer. The expected survival is estimated from US life tables matched to the group of cancer patients by age, sex, race, and calendar year. Relative survival captures all excess mortality among cancer cases including deaths attributable to treatment and as such serves as a proxy for disease-specific survival that accounts for treatment-related mortality. In calculating relative survival, we excluded women diagnosed through death certificate or autopsy, because of uncertainties in the diagnosis date. We also excluded cases with no follow-up information.

Prevalence of de novo MBC using the counting method

The prevalence of *de novo* MBC in the SEER-9 areas (counts and proportions) is calculated directly using the SEER*Stat counting method(7), which counts all women alive on 31st, December 2013 with a previous diagnosis of stage IV BC (1988–2012) in the SEER-9 areas. The method also adjusts for cases lost to follow-up. To estimate the *de novo* MBC prevalence counts in the US we applied the SEER-9 prevalence proportions by 5-year age group and race to the respective female US populations.

Modeling survival time from MBC including de novo and recurrence

To model survival for *de novo* MBC cases we estimated relative survival by age and year at diagnosis for women diagnosed with stage IV BC from 1992 to 2012 in the SEER-11 areas. To extrapolate survival beyond the observed data, as required by the back-calculation method, we fit a Weibull mixture cure survival model to *de novo* MBC relative survival data.

The mixture cure survival model assumes that a proportion of cancer patients is cured of cancer while the remaining patients die following a Weibull survival distribution. While most stage IV BC patients die of their cancer, this model is used because it allows for modeling of long term survivors and extrapolation of survival beyond the observed data. We fit a separate model to each of the 5 age groups (15–49, 45–64, 65–74, 75–84, 85–99) and used calendar year as a covariate in the model using the CANSURV software(13, 14) (https://surveillance.cancer.gov/cansurv/). Details of the model are provided in the Supplemental Materials.

Because population-level data on survival from MBC recurrence are unavailable, we use an adjustment to the *de novo* MBC survival based on a University of Texas M. D. Anderson Cancer Center (MDACC) study that included 2,881 and 643 women, retrospectively identified and diagnosed between 1992 and 2007 with recurrent and *de novo* MBC, respectively (15). The comparison of the overall survival curves for recurrent and *de novo* MBC, Figure 1 in Dawood et al. (15), showed an average risk of death for recurrent relative to *de novo* disease of 1.35 (i.e., 1.35=log(recurrent survival)/log(de novo survival)). Recurrent MBC survival was estimated by applying the 1.35 relative risk adjustment to each of the modeled *de novo* MBC survival curves (recurrent MBC survival= *de novo* MBC survival $^{\exp(1.35)}$). We also performed sensitivity analyses and provided prevalence estimates using a lower and a higher relative risk adjustment of 1.2 and 1.5, respectively.

To model survival from *de novo* or recurrent MBC we compute a weighted average of the *de novo* MBC survival and the recurrent MBC survival, i.e.,

$$\text{MBC survival} = w * (\textit{de novo}\ \text{MBC survival}) + (1 - w) * (\text{recurrent MBC survival}),$$

where w is the fraction of BC deaths that are a consequence of *de novo* MBC and (1−w) is the fraction of BC deaths that are a consequence of recurrent MBC. We use incidence-based mortality by stage in SEER to estimate w. Details of the calculation are provided in the Supplemental Materials and Supplemental Figure 1 which shows that the resulting estimated w is 0.2, implying that 20% of BC deaths in a given year originate from women diagnosed with *de novo* MBC, while 80% are deaths from women diagnosed with earlier stage BC who progressed to recurrent MBC.

Back-calculation method

We used the Mortality Incidence Approach MODel (MIAMOD) (8, 9) to estimate incidence and prevalence from BC mortality and MBC survival. The method is based on the illness-death process and two equations relating incidence, survival, prevalence and mortality. The method assumes that each observed BC death is the result of MBC, either *de novo* or recurrent. The first equation specifies mortality as the sum of prior incidence and survival and back-calculates incidence of MBC (*de novo* or recurrent), by single-year ages and single calendar years, from BC deaths and MBC survival. The second equation is used to estimate prevalence from the estimated incidence and survival. The MIAMOD software can be downloaded from (http://www.eurocare.it/MiamodPiamod/tabid/60/Default.aspx) and details

of this application are included in the Supplemental Materials. Prevalence projections from 2014 to 2020 assume constant BC mortality rates at 2014 levels and constant survival, but use dynamic population size projections for these years.

To adjust for data inconsistencies, such as underreporting of deaths and misclassification of deaths to site of metastasis as found elsewhere (11), we calibrate the back-calculation method by comparing the SEER-9 counting-method prevalence of *de novo* MBC with the one obtained from the MIAMOD method. The calibration suggests adjusting MBC survival by a factor of 0.92=exp(−0.08) to correct for 11% underestimation of the observed prevalence, i.e., $S^*_{MBC}(t)=S_{MBC}(t)^{0.92}$. Results from the calibration are shown in the Supplemental Figures 2 and 3.

Results

In 2013, the last year with observed data, we estimate a prevalence of MBC of 138,622 of which 38,897 (28%) are survivors who were initially diagnosed with *de novo* stage IV disease and 99,725 (72%) survivors initially diagnosed with stage I–III BC who later progressed to MBC (Table 1). The backcalculation method also estimates 50,344 new diagnoses of MBC in 2013, of which 12,966 (26%) are *de novo* and 37,378 (74%) recurrences, thus 3 in 4 are undocumented diagnoses of MBC. We project that by 1/1/2017 there will be 154,794 women living with MBC in the United States. Using relative risk adjustment of 1.5 and 1.2, instead of 1.35, we estimate 136,419 and 178,412, 2017 US MBC prevalence, respectively. Figure 1 shows that, based on our calculations, MBC prevalence in terms of the number of women living with MBC increased 4% from 1990 to 2000, 17% from 2000 to 2010 and is projected to increase by 31% from 2010 to 2020. Although the largest majority of prevalent cases are women who have been living with metastatic disease for 2 years or less (40%), one third (34%) have lived for 5 years or more with MBC (Figure 2).

Relative survival estimates used in the modeling included 25,935 women diagnosed with *de novo* stage IV BC from 1992–2012 (Table 2). Median survival and 5-year relative survival increased over the years especially for younger women diagnosed after 1995 (Table 2). Median relative survival time increased from 22.3 to 38.7 months and from 19.1 to 29.7 months for women diagnosed between ages 15–49 and 50–64, respectively, during 1992–1994 versus 2005–2012. The 5-year relative survival had a 2-fold increase from 18% to 36%, for women diagnosed with *de novo* MBC at age 15–49 between 1992–1994 and 2005–2012, respectively. Despite a poor prognosis there is a small but meaningful percent of these cases who survive 10-years or more; more than 11% of women diagnosed between 2000–2004 under the age of 64 years survived 10 years or more. Younger women diagnosed with *de novo* MBC have higher survival compared to women diagnosed at older ages (Figure 3).

Figure 4 compares MBC survival in SEER and in the MDACC study cohort. The MDACC cohort included 2,881 and 643 women with recurrent and *de novo* MBC respectively, retrospectively identified and diagnosed between years 1992 and 2007 and ages 17 and 91. In order to be comparable, we selected women diagnosed with *de novo* MBC in SEER in the same calendar years (1992–2007) and ages 15 through 84. In the MDACC cohort the median

age at diagnosis was 52 and 50 years for *de novo* and recurrent MBC, respectively, while in SEER the median age at diagnosis was 61 years of age. Relative survival for women diagnosed with *de novo* MBC in the SEER areas was lower than overall survival among women in the MDACC cohort. The 4-year relative survival of *de novo* MBC in SEER was 27% compared with 41% and 29% overall survival for *de novo* and recurrent MBC in the MDACC cohort, respectively. Relative survival is generally higher than overall survival for *de novo* MBC (Table 1, thus these results suggest that the MDACC cohort represents a lower-risk cohort than the general population. The absolute difference decreased with longer follow-up and 10-year relative survival was 10% in SEER versus 14% in the MDACC for women diagnosed with *de novo* MBC (Figure 4).

Discussion

Despite the progressive and incurable nature of almost all MBC, median survival after diagnosis with metastatic disease has been increasing, resulting in a growing number of women living with MBC in the United States. The increased survival is especially noted for women diagnosed at younger ages. We estimate a 2-fold increase in 5-year relative survival from 18% to 36%, for women diagnosed with *de novo* stage IV at age 15–49 between 1992–1994 and 2005–2012, respectively, translating into an increase of approximately one third in the number of women living with MBC, from 105,354 in 1990 to 138,622 in 2013. We further project that by 2017 there will be 154,794 women living with MBC in the United States.

To our knowledge, this is the first time that the number of women living with MBC in the United States has been estimated. These estimates provide a new perspective on the population burden of breast cancer and have great potential significance to the research and advocacy community working on behalf of MBC patients and their families.

Other studies have also shown improvement in survival for women with *de novo* distant disease or metastatic recurrence(16–18), attributed to improved treatment. The improvement in MBC survival may also be explained by changes in staging. A study using SEER data (19) has shown that incidence of distant BC has been increasing, especially among young women (Supplemental Figure 4). Also, incidence of stage III and unknown stage has been decreasing (Supplemental Figure 5). Thus, although survival may have increased because of improvements in treatment, part of the increase may be also due to stage migration from stage III or unstaged to stage IV or early detection of stage IV, likely due to increasing availability of better imaging techniques.

Strengths of our study include the large population size, the population-based setting, the long follow-up, and the fact that we used consistent definitions of staging and other variables across time. The calibrated back-calculation method showed a very good agreement with reported incidence and directly estimated prevalence of *de novo* MBC in the SEER areas. The calibration corrects for possible underreporting and misclassification of cause of death.

The main limitation of this study is the absence of population-based survival estimates following MBC recurrence. In order to represent survival/mortality associated with MBC

recurrence, we used a 1.35 higher risk of cancer death (inflation factor) for recurrent MBC relative to *de novo* disease based on a single-institution study conducted at MDACC (15). This factor accounts for greater susceptibility to the cancer as well as greater vulnerability to treatment morbidities due to accumulation of cancer treatments received before the point of recurrence. Other causes of death, not associated with breast cancer or its treatment are assumed to be similar between *de novo* and recurrence MBC patients. Sensitivity analyses to this assumption showed that US prevalence of MBC estimates would vary from 136,000 to 178,000 in 2017 using a higher relative risk of death (RR=1.5) or a lower relative risk of death (RR=1.2) for recurrent MBC survival compared to *de novo* MBC survival. However, we noted that SEER survival was lower than survival in the MDACC. Possible explanations may be the fact that MDACC patients were younger compared to SEER patients and that, by definition, were in treatment at a major cancer center, and therefore more likely to receive optimal care. Given these differences, collection of additional data to estimate recurrent MBC survival would be of value.

We used the adjusted 6th edition stage IV to define MBC to only include tumors that have metastasized to distant sites. If instead we used SEER historical distant stage definition, prevalence would have been higher, as some tumors without a distant metastasis are included in this definition.

At one time, a diagnosis of distant recurrence or *de novo* Stage IV meant that death from BC was likely to be imminent. Today, with the development of new therapies that target the drivers of BC, and with improved palliative care, MBC is not the immediate death sentence it once was. With optimal care, women with MBC can and often do live for years with reasonable quality of life, albeit undergoing constant treatment to keep their disease under control.

This study demonstrates that there are a large number of women in the US living with MBC and that this number has increased in more recent years, likely the result of treatment and aging of the US population. This study demonstrates a growing burden of MBC in the US. It also makes clear that the majority of MBC patients, 3 out of 4 who are diagnosed with non-metastatic cancer but progress to distant disease, have never been properly documented. Given the growing burden of MBC, it is critical to collect data on recurrence in order to foster more research into the specific needs of this understudied population(5).

In an ideal world, a cancer registry would record the experiences of all patients throughout the entire cycle of disease, enabling researchers, health policy experts and planners, providers, patients and advocates to understand the full impact of cancer. Finding ways to incorporate information on metastatic disease progression would be an important advance and a key first step towards a comprehensive assessment of the population burden of disease.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

Financial support: This work was supported by the National Cancer Institute at the National Institutes of Health. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Cancer Institute or the National Institutes of Health.

The authors would like to thank Joan Warren and Julia Rowland whose comments/suggestions helped improve and clarify this manuscript. The authors acknowledge the members of the Metastatic Breast Cancer Alliance and patients living with MBC who inspired this work and encourage readers to learn more at www.mbcalliance.org.

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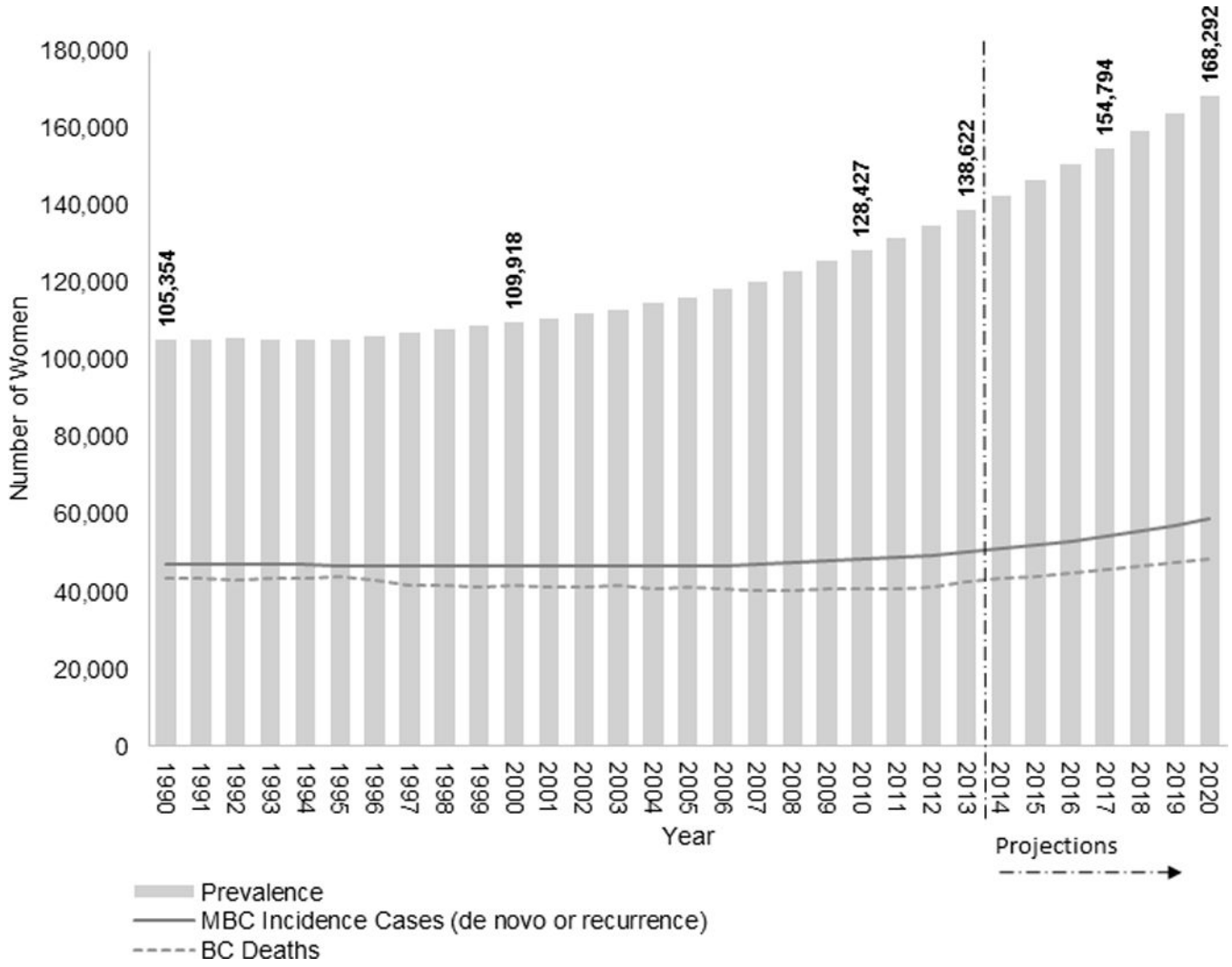

Figure 1.

Estimates and projections of metastatic breast cancer (MBC) prevalence in the United States from 1990 to 2020 (gray bars). Observed number breast cancer (BC) deaths (dashed line) as used as input in the backcalculation model and estimated number of new cases with de novo and recurrent MBC (solid line).

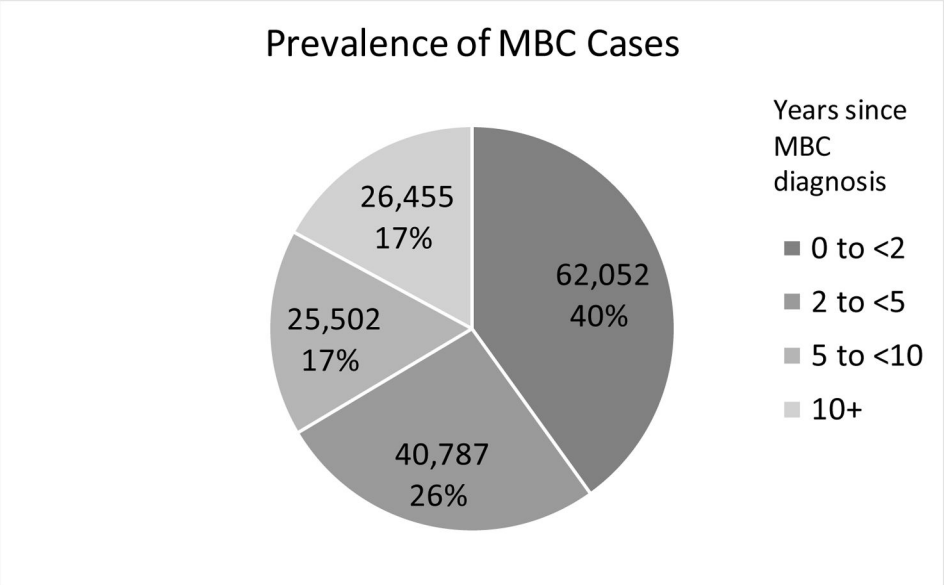

Figure 2.
Number of women in the US alive at 1/1/2017 previously diagnosed with *de novo* or recurrent metastatic breast cancer (MBC) by time since diagnosis.

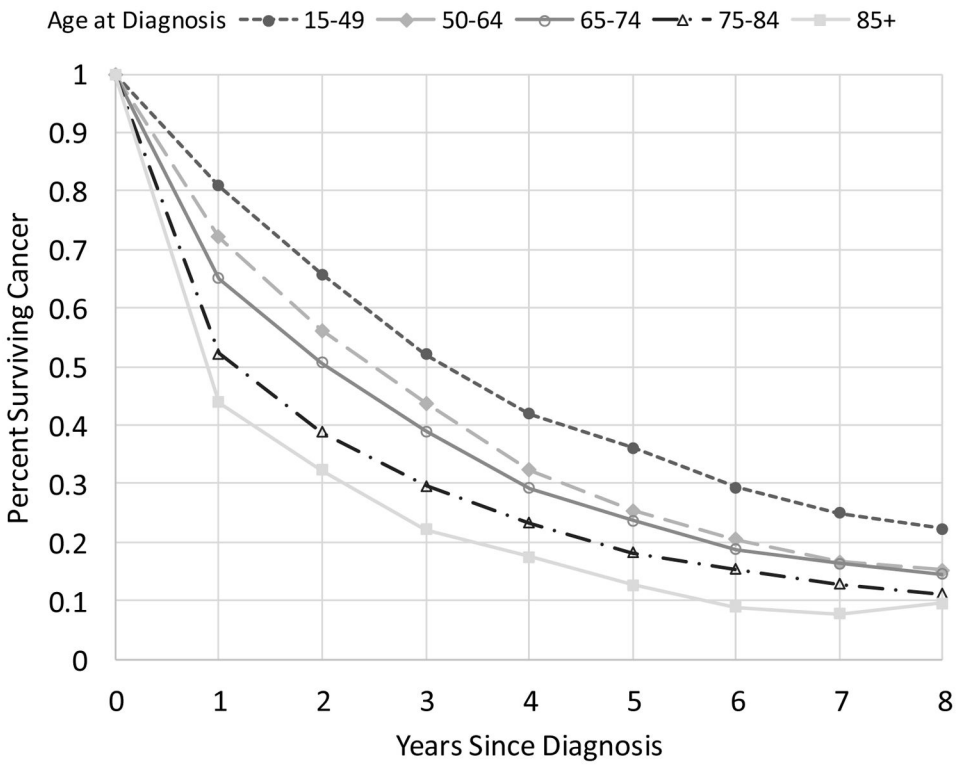

Figure 3.
Relative survival by time since diagnosis for women diagnosed with *de novo* stage IV in the SEER-11 areas between 2005–2012 at different age groups.

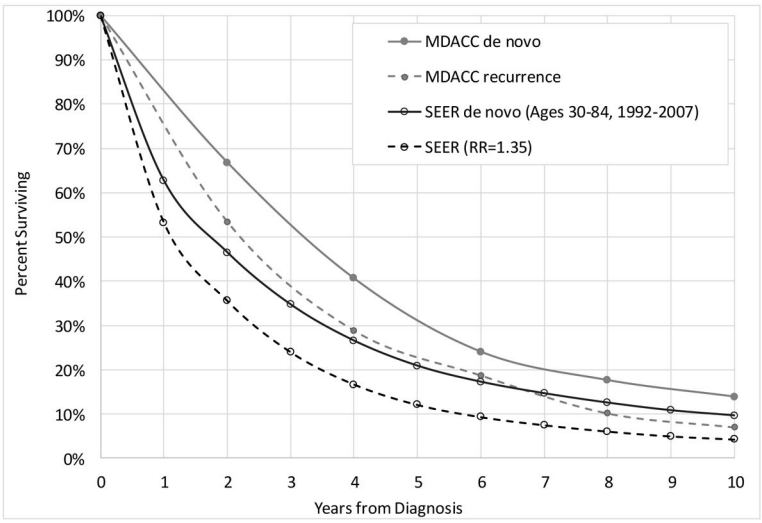

Figure 4.

Relative survival by time since diagnosis for women diagnosed with *de novo* stage IV in the SEER-11 areas in 1992–2007 at ages 15–84 (black) and the adjusted survival for recurrence stage IV for ages 15–84 based on a 1.35 relative risk adjustment (dashed black). The gray curves represent survival from a University of Texas M. D. Anderson Cancer Center (MDACC) study that included women diagnosed with *de novo* (gray) and recurrence MBC (dashed gray).

Table 1

Estimates (1/1/2013) and projections (1/1/2017) of breast cancer mortality, and incidence and prevalence of metastatic breast cancer (MBC) including *de novo* and recurrence disease in the US. Projections are based on dynamic projections of population growth and aging from the US Census Bureau and constant projections of breast cancer mortality and of MBC survival.

	Number of Women at 1/1/2013						
		BC Deaths		**MBC Incidence**		**MBC prevalence**	
Age	**US Female Population**	**Observed**	**Estimated**	***De novo* (Observed)**	***De novo* and recurrence (Estimated)**	***De novo* (Observed)**	***De novo* and recurrence (Estimated)**
15–39	52,450,844	996	976	705	1,870	1,604	4,205
40–49	21,199,116	3,530	3,416	1,422	5,129	4,736	15,684
50–59	22,400,308	7,979	8,095	2,994	9,962	8,950	30,642
60–69	17,143,155	10,071	9,888	3,200	11,481	11,002	36,194
70–70	10,011,131	8,650	8,617	2,678	9,342	7,740	27,232
80–99	7,338,871	11,216	11,176	1,967	12,560	4,865	24,665
All ages	130,543,425	42,442	42,169	12,966	50,344	38,897	138,622
	Number of Women at 1/1/2017 (Projections)						
		BC Deaths		MBC Incidence		MBC prevalence	
Age	US Female Population	Observed	Estimated	*De novo* (Observed)	*De novo* and recurrence (Estimated)	*De novo* (Observed)	*De novo* and recurrence (Estimated)
15–39	54,104,476	-	1,056	-	2,050	-	4,711
40–49	20,471,655	-	3,317	-	5,052	-	16,019
50–59	22,240,898	-	8,103	-	10,042	-	32,573
60–69	19,420,211	-	11,151	-	13,037	-	42,450
70–70	11,771,880	-	10,035	-	10,910	-	32,731
80–99	7,602,526	-	11,767	-	13,302	-	26,310
All ages	135,611,646	-	45,429	-	54,394	-	154,794

Table 2

Number of women, median overall and relative survival (RS) in months and 5-year relative survival in percent (95% C.I.) for women diagnosed with *de novo* stage IV breast cancer in the SEER-11 areas by grouped age and year at diagnosis.

			Median (in months)		5-year Relative Survival		10-year Relative Survival	
Year	Age	N	Overall	Relative Survival		95% C.I.		95% C.I.
1992–1994	15–49	430	22.2	22.3	18%	(14%,21%)	10%	(8%,14%)
1992–1994	50–64	777	18.4	19.1	15%	(13%,18%)	8%	(6%,11%)
1992–1994	65–74	598	16	17.6	15%	(12%,18%)	7%	(5%,10%)
1992–1994	75–84	442	10.1	10.9	16%	(12%,20%)	7%	(4%,11%)
1992–1994	85+	168	3.8	4.1	6%	(2%,13%)	4%	(0%,16%)
1992–1994	All ages	2,415	15.7	16.7	15%	(14%,17%)	8%	(7%,9%)
1995–1999	15–49	894	24.5	24.7	24%	(21%,27%)	11%	(9%,13%)
1995–1999	50–64	1,321	20.3	20.6	21%	(18%,23%)	10%	(8%,12%)
1995–1999	65–74	978	14.4	15.2	17%	(15%,20%)	6%	(5%,8%)
1995–1999	75–84	799	10.4	11.8	13%	(10%,16%)	7%	(5%,10%)
1995–1999	85+	292	4.7	5.5	16%	(10%,23%)	8%	(2%,21%)
1995–1999	All ages	4,284	16.5	17.7	19%	(17%,20%)	8%	(8%,9%)
2000–2004	15–49	1,307	29	29.3	29%	(26%,31%)	14%	(12%,16%)
2000–2004	50–64	2,270	24.6	25.1	24%	(23%,26%)	11%	(10%,13%)
2000–2004	65–74	1,319	18.9	20.3	20%	(18%,23%)	8%	(6%,10%)
2000–2004	75–84	1,142	10.3	11.4	15%	(13%,18%)	8%	(6%,10%)
2000–2004	85+	436	5.7	7.2	14%	(9%,20%)	9%	(3%,19%)
2000–2004	All ages	6,474	19.8	21.1	22%	(21%,23%)	10%	(9%,11%)
2005–2012	15–49	2,748	38.4	38.7	36%	(34%,38%)	-	-
2005–2012	50–64	4,861	29	29.7	25%	(24%,27%)	-	-
2005–2012	65–74	2,468	23.3	24.5	24%	(22%,26%)	-	-
2005–2012	75–84	1,820	12	14	18%	(16%,21%)	-	-
2005–2012	85+	865	6	8.2	13%	(9%,17%)	-	-
2005–2012	All ages	12,762	25.2	26.9	26%	(25%,27%)	-	-