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Endocrine therapy use in the twenty-first century: usage rates and temporal trends illustrate opportunities for improvement for South Carolina Medicaid women

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Abstract

Purpose This study examines endocrine therapy (ET) non-initiation, non-adherence, and duration by age, race, temporal trend for South Carolina Medicaid-enrolled women diagnosed with estrogen receptor-positive breast cancer between 2000 and 2014 ($N=3830$).

Methods Age, race, relative risk, and median duration of ET use were compared. Temporal trends in ET non-initiation, non-adherence, and duration were observed using linear and logistic regression models, controlling for age and race.

Results Fifty-three percent of women in the sample did not initiate ET, with highest non-initiation rates among African Americans and survivors under age 50. Of those who did initiate ET, 42% were non-adherent with a median ET usage duration of 37 months. Twenty-one percent of initiators continued taking ET for 5 years or more. There was no change in the odds of ET non-initiation from 2000 to 2004 (OR 1.02, $p=0.67$). The odds of ET non-initiation decreased from 2005 to 2009 (OR 0.81, $p<0.001$) but then increased from 2010 to 2014 (OR 1.08, $p=0.002$). There was no change in the odds of ET non-adherence from 2000 to 2006 (OR 1.02, $p=0.53$), but from 2007 to 2012, the odds of ET non-adherence decreased each year (OR 0.93, $p=0.02$). The average ET usage duration was increasing from 2000 to 2006 ($\beta=2.74$, $p<0.001$) but decreasing from 2006 to 2012 ($\beta=-1.46$, $p<0.001$).

Conclusions This study provides a realistic picture of the challenges associated with ET usage among South Carolina Medicaid breast cancer patients. It particularly highlights small improvements over time in ET usage rates, indicating more opportunities for improvement in ET initiation, adherence, and duration among younger women of lower socio-economic status.

Keywords Breast cancer · Survivorship · Endocrine therapy · Tamoxifen · Aromatase inhibitors

Introduction

With advances in breast cancer screening and treatment, the population of female breast cancer survivors in the United States continues to grow and was estimated at over 3.5 million as of January 2016 [1]. This population is expected to total over 4.5 million by 2026 [1]. An important issue for female breast cancer survivors is reducing the risk of cancer recurrence. The risk of cancer recurrence can be influenced

by many factors, including the original cancer and the initial treatment.

Endocrine therapy (ET) has been used for decades as the primary means of reducing the risk of breast cancer recurrence and improving disease-free survival in women with estrogen receptor-positive Stage 0–III disease [2]. However, non-initiation, non-adherence, and discontinuation rates remain high [3, 4]. Numerous cross-sectional studies have been published highlighting subgroups of women experiencing the highest rates of ET non-initiation, non-adherence, or discontinuation in certain populations, which have often included women younger than age 50 or older than age 70, of African American race, and/or of economically disadvantaged populations [5–11].

Even though there has been greater attention given to ET in oncology literature and practice [12, 13], a gap persists in the literature regarding how ET usage rates have changed

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over time. There is an impetus to particularly explore longitudinal patterns among populations that are known to experience special challenges related to cancer care, especially younger and economically disadvantaged women [6, 8, 9, 14]. The purpose of this study is to describe ET non-initiation, non-adherence, and duration by age, race, and temporal trend for South Carolina Medicaid-enrolled women who had estrogen receptor-positive breast cancer diagnosed between 2000 and 2014.

Methods

Data source

South Carolina Central Cancer Registry incidence data from 2000 to 2014 were used to identify the study sample and then linked with South Carolina Medicaid prescription claims and administrative data from 2000 to 2016 [15]. The data were linked by South Carolina Department of Revenue and Fiscal Affairs using probabilistic match by patient first name, last name, Social Security number, and date of birth. Data was de-identified prior to release to the researchers. Clemson University (IRB2017133) and South Carolina Department of Health and Environmental Control Institutional Review Boards approved the study.

Sample

This retrospective cohort study included South Carolina (SC) women ages 18–64 at diagnosis with Stage 0–III or unstaged estrogen receptor-positive breast cancer diagnosed between

2000 and 2014 ($N=34,791$). Breast cancer survivors who had SEER summary stage 7 cancer ($N=1,531$), who did not have estrogen receptor-positive cancer ($N=5,183$), who had prior cancer diagnoses ($N=3,016$), or whose cancer was identified through autopsy or death certificate ($N=72$) were excluded. After linking with SC Medicaid prescription data, breast cancer survivors who did not meet Medicaid eligibility inclusion criteria (i.e., no prescription data; $N=18,762$ or dually enrolled in Medicare; $N=2,397$) were also excluded. Those who were dually enrolled in Medicare were excluded because Medicare prescription claims were not available and therefore, ET usage could not be reliably tracked. After exclusions, there were 3830 breast cancer survivors included in this study. (Fig. 1).

Definition of non-initiation, non-adherence, and duration of ET usage

ET was defined as Tamoxifen/Nolvadex or one of the following aromatase inhibitors: Anastrozole/Arimidex, Letrozole/Femara, or Exemestane/Aromasin, which were identified using National Drug Codes from the Medicaid prescription claims. *Non-initiation* was defined as not having any Medicaid prescription claims in the entire study period (from 2000 to 2016). The non-initiation rate was calculated by dividing the number of women who were ET non-initiators by the total number of eligible women ($N=3830$). *Non-adherence* was defined as an ET medication possession ratio of less than 80%, meaning that the pill supply covered less than 80% of the days from the first ET prescription dispense date through the last [16]. *Duration of ET usage* was calculated as the number of months between the first and last

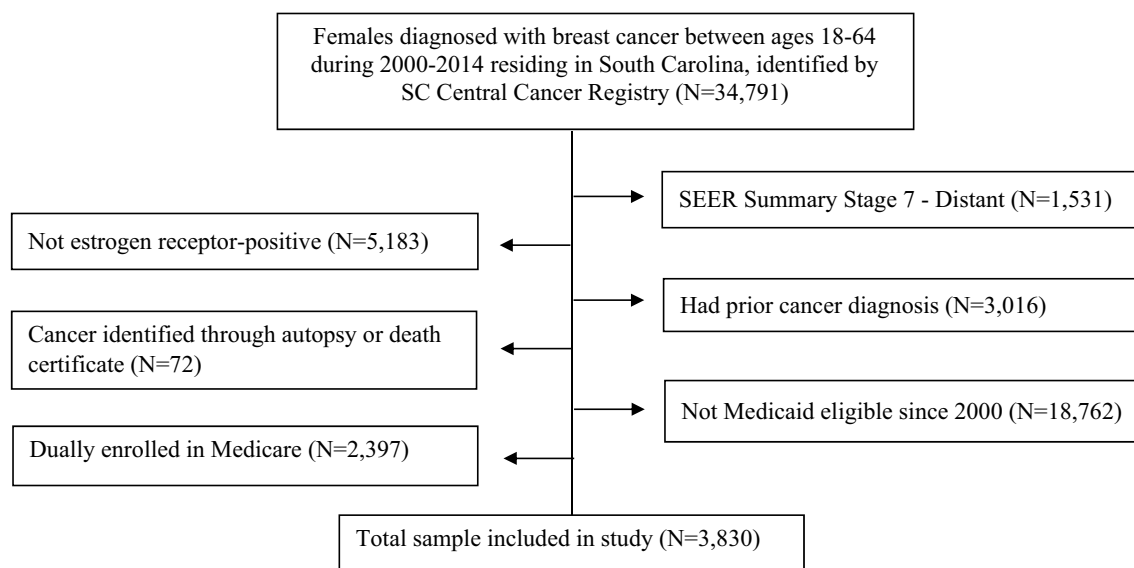


Fig. 1 Cohort selection criteria

ET prescription dispense date. The proportion of women taking ET for at least 5 years was calculated by dividing the total number of women taking ET for at least 5 years by the total number of women initiating ET. Non-adherence and duration were calculated using the date dispensed and days supplied variables from the South Carolina Medicaid pharmacy claims file.

Statistical analysis

Demographic characteristics were compared between ET initiators and non-initiators using Chi square tests. Relative risk was calculated for ET non-initiation for each of the age/race subgroups, with white/age ≥ 50 years as the reference group.

ET non-adherence and usage duration analyses were conducted among women who had filed at least one ET prescription claim through South Carolina Medicaid and who were diagnosed between 2000 and 2012 ($N = 1366$). Women diagnosed in 2013 and 2014 were excluded due to the shortened follow-up time since prescription records were only available through 2016. Chi square (χ^2) tests were used to test for a difference in non-adherence rates among age/race subgroups (i.e., White/age < 50 years, African American/age < 50 years, White/age ≥ 50 years, African American/age ≥ 50 years). Relative risk of ET non-adherence was calculated for each of the age/race subgroups, with White/age ≥ 50 years as the reference group. Kruskal Wallis tests were used to test for a difference in median duration of ET usage by age/race subgroups as previously defined.

We also examined temporal trends in endocrine therapy (ET) non-initiation, non-adherence, and duration. Temporal trend was measured by calendar year of breast cancer diagnosis. The objective was to study participants in groups by year of breast cancer diagnosis since much of the information and motivation a woman receives for taking ET in the long-term is provided in the initial conversation with a provider when the patient receives the first ET prescription.

We used logistic regression to model whether an individual initiated ET or not. We also used logistic regression to model whether an individual was adherent to ET or not. We used ordinary least squares linear regression to estimate an individual's ET usage duration in months. In each of the three models, we controlled for the covariates age (continuous variable centered at the mean) and race (0 = White, 1 = African American).

The data was first examined visually and descriptive statistics were calculated. The data did not meet the assumptions for linearity for any of the three outcomes, so non-linear time trend models were chosen. Non-initiation rates resembled a cubic pattern, so the time period was divided into three sub-periods to capture different trends occurring during these three sub-periods. Non-adherence and

duration seemed to generally increase until the year 2006 and decrease thereafter, so time was divided into two sub-periods for these analyses.

To allow for nonlinear changes in ET non-initiation over time, we used a linear spline with knots at 2004 and 2009. For non-initiation, we divided time into the periods 2000–2004, 2005–2009, and 2010–2014. To allow for changes in ET non-adherence and duration observed before and after 2006, we used a linear spline with a knot at 2006. For non-adherence and duration, we observed changes in the periods 2000–2006 and 2007–2012. Wald tests were used to determine whether the coefficients for the different time periods were equivalent. Adjusted trends were examined by generating predicted probabilities of ET non-initiation and non-adherence as well as average duration from the developed models. Stata 14.2 was used for all analyses.

Results

Initiation

There were 3830 Medicaid-eligible women who had estrogen receptor-positive breast cancer diagnosed between 2000 and 2014 who met the inclusion criteria for this analysis. Approximately half of these women (53%, $N = 2030$) did not fill an ET prescription as evidenced by Medicaid prescription claims.

Demographic characteristics of ET initiators and non-initiators were examined. (Table 1) The highest non-initiation rates were seen in African Americans (55% non-initiation) and survivors under age 50 (56% non-initiation). Compared to White women ≥ 50 , the relative risks for African Americans < 50 , White women < 50 and African American women ≥ 50 were 1.24 (95% CI 1.14, 1.36), 1.23 (95% CI 1.12, 1.34), and 1.16 (95% CI 1.05, 1.28), respectively. Non-initiation rates and risk ratios by age/race subgroups are presented in Table 2.

Table 1 Demographic characteristics of South Carolina Medicaid breast cancer survivor endocrine therapy (ET) initiators and non-initiators, 2000–2014

	Initiators ($N = 2030$) (%)	Non-initiators ($N = 1800$) (%)	<i>p</i> values
Race (%)			0.025
White	50	53	
African American	49	45	
Age (%)			< 0.001
< 50 years old	40	47	
≥ 50 years old	60	53	

The statistical differences were tested using χ^2 tests

Table 2 Endocrine therapy (ET) non-initiation rates (%) and relative ratios (95% CI) by age and race subgroups of South Carolina Medicaid breast cancer survivors

Race	Age	
	< 50 years	≥ 50 years
Rate		
White	56%	46%
African American	57%	53%
Relative risk		
White	1.23 (1.12, 1.34)	1.00
African American	1.24 (1.14, 1.36)	1.16 (1.05, 1.28)

Table 3 Endocrine therapy (ET) non-adherence rates (%) and relative ratios (95% CI) by age and race subgroups of South Carolina Medicaid Breast cancer survivors

Race	Age	
	< 50 years	≥ 50 years
Rate		
White	45%	33%
African American	55%	34%
Relative risk		
White	1.36 (1.18, 1.63)	1.00
African American	1.67 (1.43, 1.95)	1.04 (0.86, 1.27)

Non-adherence

Among all initiators, 42% ($N=755$) of survivors were non-adherent. There was a statistically significant difference in the non-adherence rates among the age/race subgroups ($\chi^2=57.91$, $df=3$, $p<0.001$). African American women younger than 50 years old had the highest non-adherence rates (55%) and were 1.67 [95% CI (1.43, 1.95)] times as likely to be non-adherent to ET compared to the most adherent group (i.e., White women age 50 or older). Risk ratios for non-adherence by age/race subgroups are presented in Table 3.

Duration

The median duration of ET usage from 2000 to 2012 was 37 months (range 0–184). Twenty-one percent of survivors ($N=288$) who initiated ET during 2000–2012 continued taking ET for 5 or more years. Five percent ($N=90$) only filled one ET prescription and did not refill after the first prescription. A Kruskal Wallis test showed there was no significant difference in median duration of ET usage by age/race subgroups ($\chi^2=1.12$, $df=3$, $p=0.77$).

Temporal trends

The non-initiation rates by year of diagnosis are presented in Table 4. We found a significant difference in the ET non-initiation trends in the three time periods examined ($\chi^2(3)=126.74$, $p<0.001$). There was no change in the odds

Table 4 Endocrine therapy (ET) non-initiation rates among South Carolina Medicaid breast cancer survivors by year of diagnosis, 2000–2014

Year of breast cancer diagnosis	White/age < 50 years ($N=1093$) %	African American/age < 50 years ($N=1034$) %	White/age ≥ 50 years ($N=872$) %	African American/age ≥ 50 years ($N=757$) %	All Women in Sample ($N=3830$), %
2000	66.2	69.2	63.4	61.5	65.3
2001	75.0	69.4	40.0	65.9	64.0
2002	69.2	68.1	61.0	73.2	68.2
2003	73.1	63.0	73.5	66.7	69.2
2004	64.1	71.1	64.9	74.4	67.3
2005	53.2	64.7	60.0	57.1	58.3
2006	52.5	50.0	43.5	74.3	53.4
2007	50.0	49.2	41.9	56.8	49.0
2008	58.7	53.7	52.5	50.0	53.4
2009	47.1	43.2	28.3	38.9	40.7
2010	41.4	46.2	32.8	38.9	40.3
2011	45.3	50.7	31.1	48.1	42.6
2012	55.4	52.5	41.9	47.3	49.5
2013	49.5	54.5	42.0	37.9	46.0
2014	58.3	54.3	46.0	39.5	50.1
2000–2014	57.3	57.3	48.2	55.4	54.5

of ET non-initiation from 2000 to 2004 (OR 1.02, $p=0.67$). The odds of ET non-initiation decreased from 2005 to 2009 (OR 0.81, $p<0.001$) but then increased from 2010 to 2014 (OR 1.08, $p=0.002$).

The non-adherence rates and median duration of ET usage by year of breast cancer diagnosis are presented in Table 5. Results showed that there was a significant difference in the ET non-adherence trends before and after 2006 ($\chi^2(2)=7.01$, $p=0.03$). There was no change in the odds of ET non-adherence from 2000 to 2006 (OR 1.02, $p=0.53$), but from 2007 to 2012, the odds of ET non-adherence decreased each year (OR 0.93, $p=0.02$).

There was also a significant difference in the ET usage duration trends before and after 2006 ($F(2,1361)=15.51$,

$p<0.001$). The average ET usage duration was increasing from 2000 to 2006 ($\beta=2.74$, $p<0.001$) but decreasing from 2007 to 2012 ($\beta=-1.46$, $p<0.001$).

Figure 2 presents the adjusted average probabilities of ET non-initiation and non-adherence by year of breast cancer diagnosis as well as the adjusted average ET usage duration by year of breast cancer diagnosis.

Conclusion

This is the first study to use longitudinal data to examine trends in ET non-initiation, non-adherence, and duration among South Carolina Medicaid-enrolled women. Our

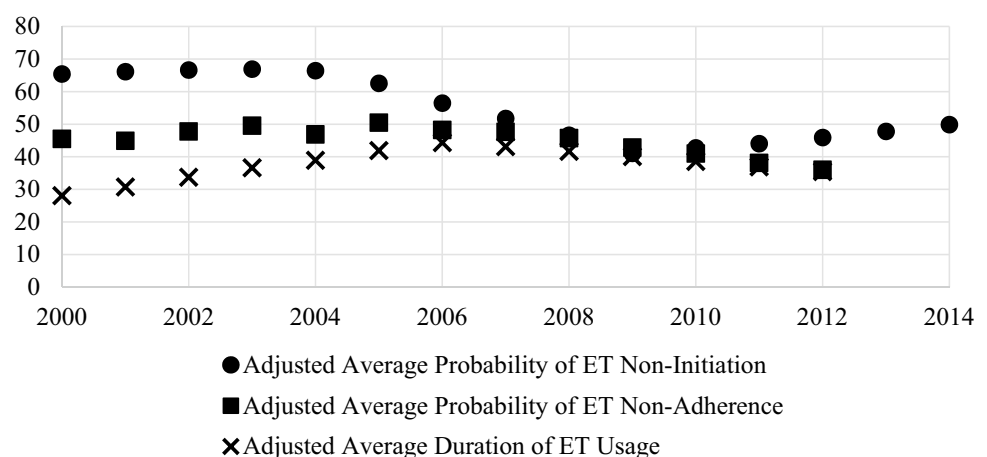
Table 5 Demographics and endocrine therapy (ET) usage non-adherence and duration patterns in South Carolina Medicaid breast cancer survivors by year of diagnosis, 2000–2014

Year of diagnosis ^a	Total no. in sample ^b	No. White, age < 50 years	No. African American, age < 50 years	No. White, age ≥ 50 years	No. African American, age ≥ 50 years	Percent non-adherent (N)	Median duration of ET (range), months ^b
2000	74	22	16	15	20	46% (34)	20.5 (0–184)
2001	77	14	22	24	15	47% (36)	22 (0–142)
2002	77	20	29	16	11	47% (36)	30 (0–167)
2003	74	18	27	13	16	50% (37)	23.5 (0–112)
2004	54	14	13	13	10	44% (24)	21.5 (0–147)
2005	78	29	18	14	15	50% (39)	34 (0–123)
2006	88	28	23	26	9	50% (44)	49.5 (0–119)
2007	103	27	33	25	16	47% (48)	46 (0–111)
2008	96	26	25	19	23	47% (45)	39 (0–90)
2009	162	45	42	38	33	42% (68)	46.5 (0–138)
2010	173	51	42	43	33	42% (72)	41 (0–79)
2011	179	47	36	62	28	34% (61)	45 (0–137)
2012	164	41	38	54	29	38% (62)	39 (0–142)

^aSurvivors diagnosed in 2013 and 2014 could only be followed for 48 and 36 months, respectively

^bSample included all female Medicaid recipients ages 18–64 at diagnosis with Stage 0–III or unstaged estrogen receptor-positive breast cancer diagnosed between 2000 and 2014 who filled at least one ET prescription. Survivors with prior cancer diagnoses, who were dually enrolled in Medicare, or whose cancer was identified through autopsy or death certificate were excluded

Fig. 2 Adjusted trends in South Carolina Medicaid breast cancer survivors' endocrine therapy non-initiation, non-adherence, and duration by year of breast cancer diagnosis



findings point to several opportunities for further investigation and possible intervention. First, 53% of the Medicaid enrollees included in the analysis never initiated treatment. This is of concern for multiple reasons. Secondly, when examining the subgroups for possible intervention to increase ET adherence, women under 50 years of age, and especially African American women under age 50, demand particular attention. Thirdly, the odds of ET non-initiation was increasing from 2010 to 2014 and the average duration of ET usage was decreasing from 2007 to 2012.

There was, however, a significant decline in the odds of ET non-adherence from 2007 to 2012, and the odds of ET non-initiation had decreased previously in the period from 2005 to 2009 with average duration increasing from 2000 to 2006. These positive findings are encouraging given the recent attention touting the benefits of ET adherence for women [6]. Because the study spans more than a decade, this data offers one of the first long-term assessments of these challenges. The opportunity is to build on the modest positive improvements seen earlier in the past decade.

Those who initiated ET had a median ET usage duration of 37 months (range 0–184), with 21% of initiators continuing ET for 5 years or more. Given ASCO's recommendations since 2014 to increase ET usage to up to 10 years in some subgroups and multiple trials showing disease-free survival benefits for those who take ET for 5–10 years [12, 13, 17–19], it is alarming that only one-fifth of initiators continued for 5 years or more and that the temporal trends showed negative results for the most recent periods concerning improvement in individual level ET initiation and duration.

We found that women under age 50 were less likely to be adherent to ET. These findings are consistent with the literature on ET usage [8], which suggests that younger women have unique considerations in their ET decision-making framework, including fertility [20] and reluctance to believe ET was a necessary part of their breast cancer treatment [21]. These explanatory factors are not fully understood and warrant further research [22].

Some important limitations accompany this analysis. First, we assumed that if a person was Medicaid-eligible and did not have a Medicaid pharmacy claim for ET, she did not take ET, as there was no other way to document ET received through other payment sources. Medicaid recipients do not typically have secondary payment sources other than self-pay, so it is not anticipated that significant missed data resulted from this limitation. Second, we assumed that if a person filled a prescription, then she took those pills. There was no way to account for whether the women actually took the medication. Furthermore, our findings were based on data from the South Carolina Medicaid population and may not be generalizable to other populations.

While promising that rates of non-initiation showed slight yet significant decreasing trends and duration showed a slight yet significant increasing trend, these results sound a call for greater improvements in ET usage rates among populations of low socioeconomic status treatment so that early real-time interventions to improve adherence can be introduced and examined. More research is needed to decipher potential factors influencing slight improvements seen since 2000 in order to capitalize on these efforts to further reduce rates of non-initiation and non-adherence and increase duration in the future. Moreover, longitudinal analyses among women with private insurance or Medicare are warranted to compare changes in ET usage rates over time among these populations. Additional analyses should also consider grouping participants by the year corresponding to the middle or end of an individual's ET duration period, where this study chose to group participants by year of breast cancer diagnosis.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval This article does not contain any studies with human participants or animals performed by any of the authors.

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