Treatment Patterns of Single Instance Breast Cancers Using Matched Real World Data Sources

Hematology/Oncology Pharmacy Association Annual Conference (HOPA 2022), Boston, MA
March 30-April 2, 2022

Treatment patterns of single instance breast cancers

INTRODUCTION

- A collaboration between the National Cancer Institute's (NCI) Surveillance, Epidemiology and End Results (SEER) Program, Emory University, and Walgreens Co. produced a database with matched Georgia SEER registry, hospitalization data, and pharmacy information at the patient level.
- Walgreens proprietary and patented patient management program, Connected Care® Oncology, referred to as CC-ONC from here on, is an evidence-based, patient-centered program that focuses on driving medication adherence and improving patient outcomes. This patented technology helps guide interactions with patients, helping them stay on their treatment and manage any possible side effects while understanding the patient perspective and proactively addressing their needs. It also captures important data that is able to be shared for informational purposes and continuity of care in order to enable a better health care experience for the patient and their health care team. However, this program is only available at centralized and decentralized specialty pharmacies.

OBJECTIVES

- To investigate this real-world data source to assess patterns of oncology treatments for first and only primary breast cancer cases in Georgia with patients matched across cancer registries, inpatient events, and antineoplastic medication records.
- To describe utilization of medications by drug therapy classes and associated hospitalization events with focus on medications within the CC-ONC program.

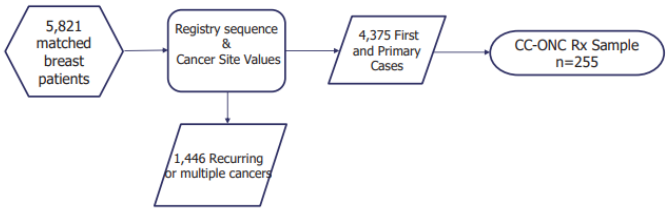
METHODS

- In this retrospective cross-sectional study, only oral antineoplastic therapies started post diagnosis and only inpatient discharge events post index antineoplastic therapy were included. Georgia SEER data included records from January 2010—December 2018. Prescription fields included sold antineoplastic medications from January 2013—December 2018 from community specialty pharmacies. Hospitalization data include data between November 2011 and December 2018 from inpatient facilities within the state of Georgia.
- We examined case characteristics at the time of cancer diagnosis and assessed antineoplastic drug classes from pharmacy, registry radiation or surgery indications at the time of diagnosis, hospitalization or ER events from discharges, and indicated deaths from registry or discharge records.

RESULTS

- Matched data for 5,821 breast cancers had 75.2% as single primary instance, and the remaining 1,446 as multiple or recurring cancers (see Figure 1). Final study sample size was 4,375 single primary breast cases, with 255 utilizing CC-ONC program medications.

Figure 1. Sample Selection Criteria



- Mean age at diagnosis was 59 years (SD 12.8) and only 37 (0.01%) patients were male. African Americans were the largest minority (34.3%), and non-white patients had a younger mean age at diagnosis than white patients, for all subtypes (see Table 1).

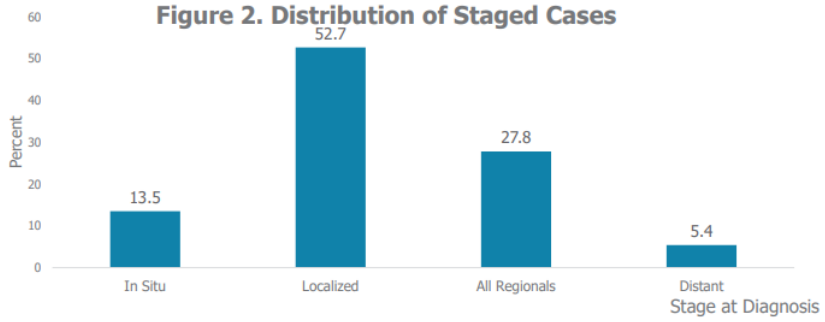
- As noted in Table 1, subtype prevalence was highest for HER2-/HR+ (70.4%) followed by HER2+/HR+ (12.7%), or for African Americans a higher number of HR+/HER2 unknowns or unknowns than other groups.

Table 1. Mean Diagnosis Age or Deaths by Cancer Subtypes and SEER Racial Categories

Background	Row Totals	Triple Negative	HER2+/HR-	HER2-/HR+	HER2+/HR+	HER2 ?/ HR+	Unknown
Col. Totals	4,375	102 (2.3%)	31 (0.7%)	3,079 (70.4%)	556 (12.7%)	519 (11.9%)	88 (2.0%)
White	2,730 (62.4%)	57.9 years Deaths 64.0% n=50	58.1 years Deaths 37.5% n=16	60.9 years Deaths 11.7% n=2,023	56.3 years Deaths 8.5% n=341	60.3 years Deaths 3.9% n=258	59.9 years Deaths 21.4% n=42
African American	1,501 (34.3%)	52.8 years Deaths 48.9% n=47	52.5 years Deaths 60% n=15	57.7 years Deaths 17.6% n=965	53.4 years Deaths 13.7% n=196	59.2 Years Deaths 5.0% n=237	59.0 years Deaths 24.4% n=41
Am. Indian-Alaskan Native	9 (0.2%)	0	0	51.0 years Deaths 0% n=5	47.0 years Deaths 0% n=1	57.0 Years Deaths 0% n=3	0
Asian Pacific	130 (3.0%)	48.6 years Deaths 80% N=5	0	55.3 years Deaths 14.1% n=85	51.8 years Deaths 26.7% n=15	56.3 Years Deaths 5.0% n=20	46.8 years Deaths 0% n=5
Unknown	5 (0.1%)	0	0	51.0 years Deaths 0% n=1	49.3 years Deaths 0% n=3	72.0 years Deaths 0% n=1	0

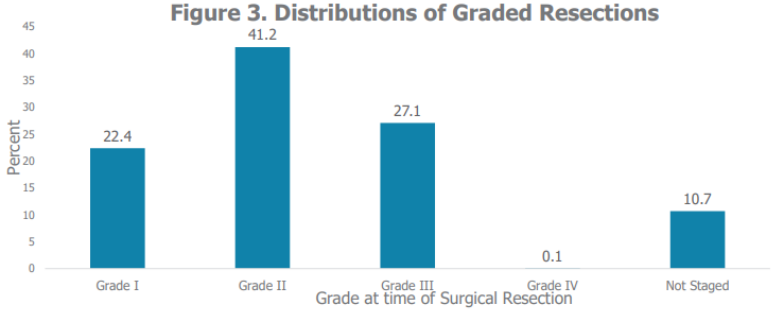
- Staging on 99.3% of cases indicated 13.5% were in situ; 52.7% were localized; 27.8% had regional designations; and 5.4% were distant. (see Figure 2.).

Figure 2. Distribution of Staged Cases



- Only 6.9% of cases did not have a surgery indication, while site-specific resection was noted for 93%.
- Primary tumor stage indications were 41.2% Grade II, 27.1% Grade III, and 21.0% Grade I; 10.7% were not staged (see Figure 3.). Grade III was the highest occurrence for most subtypes, except Grade II was highest for HER-/HR+ or hormone positive HER unknown subtypes (not shown).

Figure 3. Distributions of Graded Resections



- Including registry indication or pharmacy records, antineoplastic medications were mainly hormones (96.7%) or chemotherapy (38.1%), with immunotherapy medications present for only 9.3% of patients.
- Many patients received additional radiation therapy (59.7%) while only 26% of patients used only hormones. Use of hormone therapy was highest among patients with HER2-/HR+ (99.2%), HER2+/HR+ (89.4%), or HR+/HER2 unspecified subtypes (99.5%).
- For medications utilized, Table 2. indicates the index medications were either aromatase inhibitors (58.9%) or antiestrogens (33.4%). Just less than 3% of the total fills for 255 patients (5.8% of sample) were oral oncolytics covered under the CC-ONC program (see Table 3).

Table 2. Drug Class Distributions of Oral Antineoplastic Utilized

Medication Class	Fills	Fill %	Index Fills	Patient %
Aromatase Inhibitors	28,349	57.5	2,576	58.9
Antiestrogens	18,688	37.9	1,459	33.4
Antimetabolites	1,288	2.6	185	4.2
Cyclin-Dependent Kinases (CDK) Inhibitors	659	1.3	95	2.2
mTOR Kinase Inhibitors	101	0.2	16	0.4
Nitrogen Mustards	42	0.1	13	0.3
Tyrosine Kinase Inhibitors	53	0.1	10	0.2
LHRH Analogs	17	<.1	10	0.2
Antineoplastics Misc.	31	0.1	4	0.1
Antineoplastic Combinations	4	<.1	2	0.1
Histone Deacetylase Inhibitors	3	<.1	1	<.1
Monoclonal Antibodies	16	<.1	1	<.1
Estrogen Receptor Antagonist	5	<.1	1	<.1
Folic Acid Antagonists Rescue Agents	20	<.1	1	<.1

Table 3. Drug Class and Generic Name Distributions of CC-ONC Medications

Generic Name	Medication Class	Fills	Fill %	Index Fills	Patient %
capecitabine	Antimetabolites	638	43.4	130	51.0
palbociclib	Cyclin-Dependent Kinases (CDK) Inhibitors	640	44.1	93	36.5
ribociclib succinate		19	1.3	2	0.8
everolimus	mTOR Kinase Inhibitors	101	7.0	16	6.3
lapatinib ditosylate	Tyrosine Kinase Inhibitors	50	3.4	10	3.9
ribociclib succinate-letrozole	Antineoplastic Combinations	4	0.3	2	0.8
vorinostat	Histone Deacetylase Inhibitors	3	0.2	1	0.4
pertuzumab	Monoclonal Antibodies	16	1.1	1	0.4

- The most utilized CC-ONC program medications included capecitabine (51%), palbociclib (36.5%) and everolimus (6.3%).
- Demographics of patients on these select medications was on average 1.5 years younger, and about 10% more non-white (whites at 52.6% and AA at 42.8%).
- Clinical characteristics of this subset of patients utilizing CC-ONC covered medications trends are more severe:
    - Nearly 62% were HER2-/HR+, followed by triple negative subtype (22.4%) and HER2+/HR+ subtype (7.4%).
    - Staged levels indicated 41.6% were distant and 38.1% had regional involvement.
    - Finally, grade levels were also higher, with 51.6% Grade III and 33.6% Grade II.
    - Death rate was at 78% compared to 13.6% for full sample.
- Hospitalizations: in order to address historical differences between data sources, an analysis on hospitalizations from initial or returning index dates was examined, and without death indications (n=593 (13.6% excluded) (See Table 1 for death rates by subtypes and ethnicity).
    - This cohort had 1,027 hospitalizations among 707 (14.6%) patients and 252 patients (35.3%) had emergency type events. Mean emergency room (ER) visit rate was 1.3 events, and 2.2 mean days stay, and non-emergency hospitalization event for 455 patients indicated a mean of 1.4 events with a mean 1.3 days of stay.
    - On the subset of patients utilizing CCONC covered medications (n=56), there were 45 hospitalizations for 27 patients (48.2%). Of these patients, 12 had emergency type events, for a mean of 1.6 events per patient and 1.3 days of stay (about 1 day less than full sample); and non-emergency hospitalization events averaged 1.2 per patent, with a mean of 1.4 days of stay.
    - Comparing the rate of ER type admissions to all admissions, the CCONC subset was at 40% compared to the remaining patients at 32.8%.
    - For both groups, primary diagnosis indicated were many unique reasons (accidents, falls, infection, etc.) other than cancer (97.3% for CC-ONC subset and 94.7% for others).

Table 4. Poverty Codes Assigned to Neighborhoods Based on Census.

Census Poverty Indication	Count	Patient %
0-<5% poverty	700	16.0
5-<10% poverty	991	22.7
10<20% poverty	1,422	32.5
20-100% poverty	1,262	28.9

- 28.9% of total patients are residing in a high poverty area (see Table 4).

DISCUSSION/CONCLUSIONS

- This study found that most patients in the data sets were on oral antineoplastics that were not included in the CC-ONC program. This would be expected as hightouch patient management programs are typically reserved for complex therapeutic regimens.
- For single instance breast cancers within the state of Georgia, aromatase inhibitors and antiestrogens were the most utilized antineoplastics, but radiation therapy was also a treatment for 59.7% of patients.
- The subset of patients utilizing CC-ONC tended to have more severe disease indications, experience multiple therapeutic interventions, which is not surprising given the severity of stage and death rates.
- Considering these results, additional tools and resources such as refill reminders, new to therapy interventions, and financial assistance available in community pharmacies should be leveraged to help patients on hormone therapy stay adherent to therapy and could be prioritized by zip codes in underserved communities.
- Combining registry, hospital, pharmacy data sources can identify practical insights to improving oncology care. Specialty pharmacy programs managing oncology patients should include screening for risk factors associated with adverse outcomes to help manage cancer care.

AMA Citation:
Staskon, F, Havern, L, Kirkham, H, Broadus, A. Treatment Patterns of Single Instance Breast Cancers Using Matched Real World Data Sources. Presented at the Hematology/Oncology Pharmacy Association 2022 Annual Conference (HOPA 2022) March 30-April 2, 2022 in Boston, MA.

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This research was approved by a Georgia Department of Heath IRB (April 2019) and funded internally by Walgreen Co. and all authors are employees of Walgreen Co..