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A RETROSPECTIVE ANALYSIS OF PRIMARY BREAST CANCER SURGICAL PROCEDURES (MASTECTOMY VS. BREAST CONSERVING SURGERY) PERFORMED ON WOMEN LIVING IN RURAL AND URBAN COUNTIES IN SOUTH CAROLINA

By

Talitha M. Massaquoi

A doctoral project submitted to the faculty of the Medical University of South Carolina

in partial fulfillment of the requirements for the degree

Doctor of Health Administration

in the College of Health Professions

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Abstract of Doctoral Project Presented to the Medical University of South Carolina In Partial Fulfillment of the Requirements for the Degree of Doctor of Health Administration

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Chairperson: Daniel Brinton, PhD Committee: Mary Dooley, PhD Eva Karp, DHA, MBA RN-BC, FACHE

Abstract

Women dealing with a diagnosis of breast cancer may be challenged when attempting to seek and obtain medical care while living in a rural community. It is not known whether geography impacts the decision-making process for women considering elective breast cancer surgery (mastectomy versus breast conserving surgery (BCS)) in South Carolina. We performed a retrospective analysis of breast cancer surgical options offered to women to examine if a difference exists in both rural and urban settings. Although there was a higher proportion of women in South Carolina who elected to undergo a mastectomy instead of BCS (4,416 [79.5%] vs. 1,139 [20.5%]) no difference was noted in the type of surgery performed based on the woman's geographical location.

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CHAPTER I INTRODUCTION

1.1 Background and Need

The rising incidence of breast cancer (BC) affecting women living in the United States has steadily increased over the last few decades at an alarming rate. The increase in BC rates has signaled a public and national health crisis (Bazzi, et al., 2023) as it has begun to affect many women of various ages throughout their lifespan. Breast carcinoma, also known as Malignant Neoplasm of the Breast, is the second most diagnosed cancer to affect women living in the United States; and BC is the second leading cause of mortality for women in the U.S. following lung cancer (Gehlert et al., 2021). In 2022, there were approximately 290,00 new cases of invasive breast cancer diagnosed in the United States; and 43,000 women died from breast cancer according to the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) program (Chen et al., 2023). A thorough assessment and analysis of breast cancer statistics acknowledge that racial disparities and inequities exist within this primarily femaledominated disease (Babatunde et al., 2020; Yedjou et al., 2019). Women of European descent experience a higher incidence of breast cancer than women of African or Hispanic descent (Chen et al., 2023). Unfortunately, women of African descent are more likely to be diagnosed with BC before the age of 45 with an advanced stage and aggressive tumor than women of European descent (Grabinski & Brawley, 2022). Despite the promotion of early breast cancer screenings and diagnosis, BC has become the primary leading cause of death for Black and Hispanic women living in the United States (Gianquinto et al., 2022; Gehlert et al., 2021).

Despite numerous advances made in breast cancer care and medical management, significant disparities continue to be highlighted throughout our healthcare system which have impacted all women from various ethnic backgrounds. Some of the differences have included the 8 detection of breast cancer through screening or diagnostic mammograms, the lack of scheduling surgical procedures within an appropriate timeframe, and the prescribing of medical care that is consistent with U.S. national standards, i.e. follow-up care with either radiation or chemotherapy treatments; or the prescribing of oral medical treatments to prevent reoccurrence (Chen et al., 2023) in the future. Unfortunately, the women of South Carolina are not immune to these effects. Women living in the state of South Carolina have been subjected to some of the largest healthcare disparities in our nation (Samson et al., 2016). South Carolina's statistical rates for BC are consistent with reported national statistics, but the mortality rates far exceed the reported national statistical rates (Babatunde et al., 2021). As a result of these noted differences in care, the focus has shifted toward prompt and timely care administered to this population as we know these factors significantly impact and improve patient outcomes and survival.

1.2 Problem Statement

South Carolina, located in the Southeastern part of the United States, comprises 46 rural and urban counties dispersed throughout four geographic regions: Upstate, Midlands, Pee Dee, and Low Country. According to the U. S. Census Bureau, South Carolina is home to more than five million people, and women compose 51.3% of the current population. The South Carolina Department of Health and Environmental Control has reported 4,545 new cases of breast cancer and 751 deaths from breast cancer in 2019.

Although no specific cause has been identified as the main contributor to the development of breast cancer, long-term exposure to the circulating hormone, estrogen, has been thought to play a role in breast tumor development (Yue et al., 2010). Several risk factors have been identified and are believed to contribute to the increase in the incidence and prevalence of BC development. Here are a few of the nonmodifiable risk factors for BC: female sex, age, density 9

of breast tissue, personal history of breast cancer, or family history of breast or ovarian cancer. Several modifiable lifestyle choices include the elective use of hormone replacement therapy, cigarette smoking, dietary habits, alcohol ingestion, obesity, and lack of physical exercise (Gajbe et al., 2022). Although aggressive changes in individual lifestyle choices or behaviors may not inhibit the development of BC disease or produce marked or noticeable changes in research outcomes, the focus has shifted toward minimizing the impact of factors related to the Social Determinants of Health (SDoH).

Even though BC is the second most diagnosed cancer in women, the use of mammography screening for early detection has proven beneficial in changing the course of breast cancer management. In affiliation with local healthcare systems and health centers throughout South Carolina, the communities are offered early breast and cervical cancer screenings through The Best Chance Network. The ability of diagnostic mammograms to detect and discover smaller tumors may have contributed to an increase in breast cancer rates during the last few decades. However, the early detection of breast cancer prevents a delay in receiving appropriate medical treatment. Breast cancer tumor staging at diagnosis becomes the principal factor in determining the course of medical treatment and prognosis. Earlier detection and diagnosis of breast cancer changes the course of breast cancer management for women through earlier treatment and access to care and enhances overall life expectancy for breast cancer patients. Geographical differences have been cited in breast cancer treatment plans and care rendered. Women living in South Carolina are disproportionately diagnosed with breast cancer and this researcher is most interested in discovering if geography influences the surgical options offered and performed on women diagnosed with BC who live in rural and urban settings throughout the state.

1.3 Research Hypotheses and Questions

This study is concerned with the surgical aspect of breast cancer management. Prior research studies have shown that patient survival outcomes for women undergoing surgical mastectomy versus partial lumpectomy (Breast Conservation Surgery or BCS) in addition to radiation therapy produced equivalent patient outcomes (Landercasper et al., 2019; Magnoni et al., 2021). This study will seek to explore if a difference exists in the rates of mastectomy versus BCS elected by women residing within the state of South Carolina. The major focus of interest will be based on geographical location (rural versus urban settings) through the tracking of zip codes, to determine if geography impacts the surgical options offered and performed on women in South Carolina faced with a diagnosis of malignant breast neoplasm. This researcher proposes that geographical location may influence a breast cancer patient's surgical decision to elect a mastectomy versus a partial lumpectomy.

My proposed research questions are:

1). Is there a correlation between the types of breast cancer surgery performed in South Carolina based on geographic location?

2). Are the rates of surgical mastectomy higher than BCS rates in rural counties versus urban counties in the state of South Carolina?

3). Did the rates of surgical mastectomy increase over time during the study period 2018 through 2021 in the state of South Carolina?

The results of this study could benefit women in the future from all ethnic backgrounds diagnosed with malignant neoplasms of the breast, through the development and implementation of interventions and health policies that encourage early surgical interventions and medical 11 treatments for women living in South Carolina that adhere to and follow national guidelineconcordant care. Focusing on decreasing the disparities or gaps in care, healthcare systems could incorporate new medical practices for their physicians and advanced practice providers who deliver care to diverse community members and contribute toward an overall impact on population health. The outcomes of this study hope to minimize but most importantly, eliminate disparities in breast cancer for all women by promoting an emphasis on the importance of receiving medical treatment in a timely fashion after detection and decreasing the mortality rates of breast cancer for women living in South Carolina. In addition, this study may shed light on other factors that affect a woman's decision to elect to have a total mastectomy versus a partial breast lumpectomy or BCS.

1.4 Target Population

This project's target population will include all women living in South Carolina, aged 40 through 85, diagnosed with malignant neoplasm of the breast, (ICD-10 C.50). This study will analyze and evaluate breast cancer data collected retrospectively from South Carolina's All-Payer Claims Database, from 2018 to 2022. Surgical excisions of cancerous lesions or breast tumors have become a front-line treatment in almost every stage of breast cancer care, except for metastatic breast cancer- Stage IV, where surgery may be performed for palliative treatment only. Therefore, women from all ethnic backgrounds, diagnosed with Breast Cancer Stages 0, I, II, III, and IV living in South Carolina will be included in the study population.

CHAPTER II LITERATURE REVIEW

2.1 Breast Physiology

The incidence and prevalence of breast cancer (BC) affecting women living in the United States has risen steadily since 2018. Breast cancer remains the second most common cancer diagnosis and cause of cancer-related deaths for women living in the United States (Trayes & Cokenakes, 2021). Early detection of breast cancer through the breast imaging techniques of digital mammography, ultrasound sonography, and magnetic resonance imaging (MRI) have been shown to increase life expectancy, decrease mortality, and contribute towards a more favorable prognosis (Le-Petross et al., 2023) for women diagnosed with this disease. The treatment of breast cancer involves the collaboration of a multidisciplinary healthcare team. Comprehensive and quality-enhanced breast cancer care comprises team members and leaders from diverse medical, surgical, and radiation oncology specialties. These healthcare professionals are leaders within their respective fields lending their clinical expertise, experience, and astute skills to manage this multidimensional disease while promoting the best outcome for the patient.

Breast tissue occupies most of the upper anterior and lateral walls of the chest extending from the level of the second or third rib down to the level of the sixth or seventh rib. Female breasts develop in an anterior lateral position on the chest wall and are bordered posteriorly by the pectoralis and rectus abdominus muscles. Also known as mammary glands, the breasts become active in response to secreted hormones, such as estrogen, progesterone, and prolactin; as well as certain growth factors, which are important to the development, maturation, and size of female breast tissues and for changes that occur at different periods during a female's life cycle. Breasts are divided into four quadrants: upper inner, upper outer, lower inner, and lower 13 outer. The upper outer quadrant of the female's breast is the most common area for tumors to develop as this quadrant occupies most of the breast tissue and volume (Gajbe et al., 2022).

2.2 Understanding Breast Cancer

Breast cancer is a heterogeneous disease with diverse histopathology, genetic variation, molecular subtypes, and clinical outcomes. Because breast cancer is so diverse, each tumor may possess many descriptive characteristics. BC can be categorized as noninvasive, invasive, or both, and tumorous lesions can be classified as multifocal or multicentric, involving more than one location or type of lesion in the specified breast. A diagnostic mammogram may detect breast cancer or breast tissue abnormalities; however, a breast cancer diagnosis is not validated until a tissue specimen is obtained and dissected by microscopic analysis to confirm the disease (Le-Petross et al., 2023). Microscopic analysis and assessment of breast tissue specimens allow pathologists to differentiate, compare, and describe the appearance of breast tumor cells versus normal breast cells. Pathologists describe breast tumor cells in three grades based upon appearance, tumor growth rate, and disease severity: Grade I, well-differentiated or low-grade tumor is thought to be a slowly growing breast tumor not likely to spread to other organs; Grade II, moderately differentiated or intermediate grade tumor; and Grade III poorly differentiated or high-grade tumor is thought to grow at a rapid pace and is more likely to spread to nearby surrounding organs.

Breast cancer is categorized into four subtypes: Luminal A, Luminal B, HER-2 (human epidermal receptor factor 2) positive, and Triple Negative. These subtypes are determined by the tumor's molecular properties and the hormone status (Watkins, 2019). If tumor analysis detects the presence of hormones, the tumor is classified as hormone receptor-positive or sensitive. Breast cancer tumor cells in the Luminal A subtype exhibit hormone-positive receptors for 14

estrogen (ER) and progesterone (PR) but negative hormone receptivity for human epidermal growth factor receptor 2 (HER-2). The prognosis for this subtype is good. In the Luminal B subtype, breast cancer tumor cells secrete hormone-positive receptors for estrogen and/or progesterone but hormone receptivity for HER-2 can have either positive or negative markers. The prognosis for Luminal B is fair. In the third subtype, HER-2, estrogen and progesterone markers are negative, while HER-2 receptors exhibit positive markers; the prognosis for HER-2 subtype is poor. The final subtype is called Triple Negative Breast Cancer (TNBC). In this subtype, the tumor lacks any of the hormone receptors (estrogen, progesterone, or HER-2), owing to its' respective name of "Triple Negative" Breast Cancer. Unfortunately, with the TNBC subtype, breast cancer is not currently curable, although it may respond to systemic chemotherapy for palliative care. A diagnosis of TNBC carries a poor prognosis for life expectancy.

2.3 Breast Cancer Development

Although breast cancer can develop in males and females, the most common risk factors for developing breast cancer disease are advancing age and the female sex. Research data have revealed that the incidence of breast cancer in women occurs more commonly in the postmenopausal phase of life with increasing age. Other known risk factors include early menarche before age 13, nulliparity, late menopause, a personal family history of breast or ovarian cancer, the use of hormone replacement therapy, a personal history of radiation therapy to the chest, a high body mass index (BMI), being a carrier of the breast cancer gene mutations, (i.e., BRCA 1 and BRCA 2), and being a carrier of the autosomal dominant conditions Cowden Syndrome and Li-Fraumeni Syndrome. Notably, 75% of women diagnosed with breast cancer disease rarely carry any identified known risk factors (Watkins, 2019). Common clinical presentations of breast cancer are the detection of a palpable breast or axillary lump or mass, skin dimpling of the breast resembling an orange peel, an inverted nipple, nipple thickening, bloody nipple discharge, erythema or redness of the skin, lymphadenopathy, an unexpected or unplanned weight loss, and pain in any area of the breast. Evidence-based practices currently endorse the use of mammography as the gold standard for the early detection of breast cancer. Mammography serves as a screening tool for breast cancer in asymptomatic women and is also used to evaluate and assess breast tissue abnormalities (Le-Petross et al., 2023). This diagnostic tool has served to increase the detection of breast cancer in its early stages and has promoted prompt medical treatment in the management of this disease. In the United States, the increased use of mammography has potentially contributed to the increased incidence of breast cancer because this diagnostic tool can detect smaller tumors (Bazzi et al., 2023). The early detection of breast cancer is vital because it is associated with earlier medical and surgical treatments and a more favorable prognosis.

2.4 Classification of Breast Cancer Stages

Once a breast tumor diagnosis has been confirmed by tissue analysis, the tumor can be assigned a breast cancer stage. Breast cancer staging is dependent upon tumor size and location, axillary lymph node involvement, and the presence or absence of metastatic disease. In their breast cancer staging guidelines, the American Joint Committee on Cancer (AJCC) designated five stages of breast cancer disease; those stages are used to help determine a patient's prognosis: Stage 0 is a noninvasive breast cancer, also called Ductal Carcinoma in Situ (DCIS); the breast tumor is local and has not infiltrated into surrounding tissue. This early stage of breast cancer is only detected within the breast ducts or lobules and carries a very high cure rate. Stage I is an early invasive but nonmetastatic breast cancer. In Stage I, the cancer has invaded surrounding breast tissue but has not invaded the lymphatic system; this stage carries an excellent prognosis for survival. Stage II tumors are an early invasive, nonmetastatic breast cancer; during tissue biopsy analysis, tumors are detected in the breast tissues and the regional lymph nodes of the lymphatic system. Although the tumor remains within the breast, metastasis to the axillary lymph nodes has occurred. Despite its lower staging, Stage II breast cancers are often associated with a poor prognosis. Stage III breast tumors are advanced, local, large tumors that are nonmetastatic; despite treatment, Stage III breast tumors lack a favorable prognosis. Stage IV breast cancers are aggressive metastatic tumors that have infiltrated other organs; Stage IV tumors are amenable to treatment but not curable, and they carry a less-than-favorable prognosis (Trayes & Cokenakes, 2021). The stage of breast cancer directs the medical management and, if necessary, surgical treatment of patients. The treatment of breast cancer is individually tailored to the histological markers, size of the tumor, and the stage of the tumor at diagnosis. Breast cancer treatment includes hormone therapy, systemic chemotherapy, radiotherapy, and /or surgery.

2.5 Surgical Options for Breast Cancer Disease

Currently, two options are available for the surgical management of breast carcinoma in women diagnosed with the disease, depending on the stage of breast cancer and when a diagnosis was confirmed. Initial surgical management of breast carcinoma was treated by the surgical resection of the entire breast tissue, known as a mastectomy, which dates to the early 18th century. Advances in medicine and aseptic techniques over the years perfected the surgical approach to performing a mastectomy; breast cancer excision involved the removal of the entire breast and the chest wall muscles as well as complete dissection of all metastatic axillary lymphatic nodes. However, this surgical technique was very disfiguring and left the woman with

less of an aesthetic appearance, affecting the mental psyche of women, and did not significantly "improve overall survival" (Lukong, 2017); thus, other medical and surgical options were explored to manage this disease. The advent of breast conservation therapy through breast lumpectomy provided an option for women to have tumorous tissues of the breast surgically excised while maintaining a more symmetrical appearance. Several studies over the years have revealed no significant difference in the overall rate of survival after breast conservation surgery (lumpectomy) plus radiation therapy versus a complete mastectomy (Munoz et al., 1986; Landercasper et al., 2019). If they are suitable candidates, breast cancer patients today are given the option to undergo a complete mastectomy or to have breast conservation surgery.

A mastectomy is the surgical removal of all cancerous breast tissues from the affected ipsilateral breast. Surgical mastectomy can serve dual purposes to treat breast cancer or prevent breast cancer when the contralateral breast is surgically removed prophylactically. Undergoing a surgical mastectomy involves the surgical excision and removal of all breast tissue, mammary glands and ducts, areola, and nipple on the ipsilateral or affected side. The other surgical option for women to treat breast cancer is to elect to have a lumpectomy, also known as breast conservation surgery (BCS). A lumpectomy involves the surgical excision of the tumorous part of the breast, including the surrounding margins of normal breast tissue and lymph nodes (Gajbe et al., 2022). The lumpectomy can be characterized by the amount of diseased breast tissue removed and can be categorized as a partial mastectomy, segmental mastectomy, or quadrantectomy. The overall goal of undergoing a lumpectomy involves the surgical removal of a distinct lump of breast tissue that is assumed to contain malignant breast cancer cells before the invasion of surrounding breast tissues and other bodily organs can occur. A successful partial mastectomy occurs through guided collaboration between a surgeon and a pathologist who confirms clear tissue margins from the excised breast tissue samples obtained during surgery. Current research trends support that there is no statistical difference in the five-year survival rate of women suffering from breast cancer who have had a lumpectomy with radiation therapy versus a mastectomy (Munoz et al., 1986).

2.6 Social Determinants of Health (SDoH) Impacts on Breast Cancer

Healthcare disparities in breast cancer management have been thoroughly documented throughout the medical literature. Research over the years has shown that significant differences exist in prevalence, incidence, breast cancer staging, survivability, mortality, and medical treatment for breast cancer. These studies have highlighted the importance of shifting the focus from breast cancer prevention to the identification of contributing SDoH factors: housing and poor nutrition, environmental conditions, access to medical facilities, and social habits of the individual that are possibly impacting the development of breast cancer. Findings from those studies also prompted healthcare facilities to promote health education that teaches women how to perform early detection methods, such as self-breast examinations, (SBE); research findings also have urged the yearly use of mammography for women aged 40 or older. Educational interventions to increase patients' knowledge also teach women about the causes of breast cancer, the symptoms, disease detection, and medical and surgical treatment options. With increasing innovations in oncology care, attention has turned to identifying women with highrisk factors for BC: a family history of breast cancer, gene-specific biological markers, and those women who come from high-risk racial and ethnic backgrounds. To level the playing field for women of all racial and ethnic backgrounds, breast cancer research recently shifted to focusing on the racial disparities reported through well-documented breast cancer statistics. It is well documented that SDoH factors can impede care for women from certain ethnic backgrounds

diagnosed with breast cancer, thus preventing them from receiving timely and equitable healthcare services. Through research, many of these multifactorial factors and their effects on society have only begun to be understood by healthcare professionals and how they have affected these fragile populations.

Although significant advances have been reported in the medical management of breast cancer disease, decades of research support the notion that variances continue to exist among various ethnic populations (Grabinski et al., 2022). To address those disparities, studies have proposed creating a diverse healthcare workforce that reflects the population it serves. Developing a trusting relationship between patients and medical professionals who resemble their communities would foster greater access for women to medical personnel, medical facilities, and healthcare services. Culturally sensitive care can be enhanced by providing medical information about breast cancer to at-risk communities through improved screening and patient care and collaboratively, through affiliations with community resources.

CHAPTER III METHODOLOGY

The purpose of this study focuses on investigating the concept of rurality and its impact on a woman's decision to consent to either a surgical mastectomy or surgical lumpectomy as her primary surgical operation with the hope of curing breast cancer. The focus of this study will discuss how rural versus urban residential living may impact the decision-making process for women living in the state of South Carolina. For our research purposes, this investigation will focus on rural health as it relates to healthcare delivery in rural environments. In conjunction, the use of the term rurality will be based on population size, population density, or geographical proximity to urban (metropolitan) areas and how the social determinants of health factors can affect healthcare services and delivery within these environments. In a recent study performed by Benedict et al., (2001) the rates of surgical mastectomy were almost double the rates of breast conservation surgery or lumpectomy with potential factors identified that could influence the woman's surgical decision. I am interested in learning if the geographical differences oftentimes found between rural and urban healthcare settings have an impact on the surgical options offered to patients due to limited healthcare providers/ specialists being readily available to address and service these communities.

The statistical data for this retrospective study will be gathered from the All-Payer Claims Database (APCD) directed by the University of South Carolina. This data will then be analyzed to identify specific breast cancer healthcare claims, and this information will be categorized based on the ICD-10 classification system, for diagnosing and procedure coding for malignant neoplasms of the breast. The All-Payer Claims Database collects data from multiple private, public, and governmental payers (health insurance carriers) in South Carolina, despite South Carolina law not enforcing compliance with a state-issued mandate for claims data collection. Public and private claims data arise from employer-sponsored insurance companies, managed care organizations, and Medicare and Medicaid government-based health insurance programs. Using the APCD will allow this investigator to evaluate and determine if a difference exists between the breast cancer surgical options offered and performed to treat breast cancer for women living in South Carolina.

3.1 Hypothesis

The research hypothesis is as follows: There will be no difference in mastectomy rates between women living in rural areas versus urban areas in South Carolina. Analysis of the statistical results will reveal if a relationship exists between surgical options offered (mastectomy or BCS /lumpectomy + radiation therapy) and surgical options delivered to women living in rural counties in South Carolina.

3.2 Research Design/Method

This study will use a retrospective, quantitative research approach that includes a multivariable analysis of the data for South Carolina extracted from the All-Payer Claims Database. Based on an analysis of data from this database the investigator will calculate the incidence rate of breast cancer and evaluate the number of breast cancer surgical interventions performed in all 46 counties in South Carolina. We will collect data that includes all hospital inpatient admissions and outpatient ambulatory surgical admissions collected between the years 2018 through 2021, specifically for breast cancer surgeries (mastectomy or BCS).

3.3 Sample Selection

Breast cancer population-based screening guidelines recommended by the National Cancer Institute advise mammography in women aged 40 years and older who are considered to 22 have an average risk for breast cancer development to undergo mammography screening every 1 to 2 years (LePetross et al., 2023). Our sample population will include all female residents diagnosed with breast cancer, between the ages of 40-85 years old. Our main goal of the study is to include women from every ethnic background, diagnosed with breast cancer. Breast cancer treatment has shifted to individualized and tumor-specific care which is based on clinical and pathological presentations. Breast cancer in Stages 0, I, II, and III may require surgical excision of the breast tumor, medical interventions via hormone therapy, systemic therapy (chemotherapeutics), or irradiation therapy. Female residents diagnosed with Stage IV Breast Cancer will be excluded as these cancers may not be considered operable for a curative goal rather than surgery recommended for palliative therapy. The stages of breast cancer and their identifying characteristics will be displayed in Appendix B.

All breast cancers are malignant tumors or lesions. For purposes of this investigation, the term malignant will imply the potential of the cancerous lesion to spread to other body parts and/or organs and the severity of the disease will not be distinguished in this study. Female candidates residing in either rural or urban counties in South Carolina during the years 2018-2021 will be included in the study if they were surgically treated with breast conservation surgery or mastectomy for BC disease. To define the dependent variables for this study, the following descriptive medical terms were used to delineate breast conservation surgery: lumpectomy, quadrantectomy, partial mastectomy, segmental mastectomy, and breast-sparing surgery. Breast conservation surgery includes the excision of malignant breast tissues and post-surgical administration of radiation therapy. Patients treated by a surgical mastectomy will include those who have undergone a modified radical mastectomy or simple mastectomy on either ipsilateral or contralateral sides with sentinel lymph node or axillary lymph node

dissections. This study aims to clarify whether a patient's geographical location affects the woman's primary decision to undergo breast preservation surgery (lumpectomy) or unilateral/bilateral mastectomy. The findings could help breast cancer practitioners screen, diagnose, and treat at-risk patients in the future. Exclusion criteria are as follows: women who initially elected to undergo a lumpectomy but were later surgically upgraded to a mastectomy, or who needed repeat surgery to remove more breast tissue; and women with a reoccurrence of the primary breast tumor, post-primary surgery; women with secondary breast cancers; men diagnosed with breast cancer.

3.4 Data Set Collection

This study will be conducted using a retrospective, quantitative research design approach using data specific to South Carolina residents and captured by the All-Payer Claims Database. This investigator hopes to calculate the rates of breast preservation surgical options listed by county with a specific focus on capturing all hospital admissions and outpatient surgeries presenting for breast cancer treatment. The researcher with then analyze the data to extract pertinent information relating to the dependent and independent variables identified as points of interest for this study.

3.5 Independent and Dependent Variables

The dependent variables will be categorized as either mastectomy or BCS/partial lumpectomy. The independent variables of interest for this study will focus on geographical location, age, and income level. Rurality (rural versus non-rural) is an independent variable of particular interest; the investigator is especially interested in exploring the possible connection between geographic location and surgical options offered to these communities. Other independent variables highlighted in this study are race, the Charlson Comorbidity Index, the healthcare setting where care was delivered (hospital inpatient or ambulatory surgical center), and the cost of the surgical procedure.

3.6 Statistical Analysis

This study will undergo bivariate analysis, using standard statistical tests: Chi-squared, Fisher's Exact, and Wilcoxon-Mann Whitney tests. The multivariable logistic regression model will be used to predict that a relationship between the dependent and independent variables exists. The overall outcome of this study hopes to conclude that the number of breast mastectomy cases exceeds the number of breast conservation surgeries within the state of South Carolina based on geographical location. Rurality will be the main predictor of the study's outcome. The covariates of age, race, and Charlson Comorbidity Index will always be continuous therefore they cannot be manipulated to affect the dependent variable. This model allows the investigator to interpret results showing how the independent variable impacts the dependent variable.

3.7 Protection of Human Subjects

All information gathered from contributing databases are encrypted to ensure anonymity. The use of archival medical claims data will help to further protect the identity of any PHI (Protected Health Information) and medical claims data collected to prevent linking these data to specific individuals. These protective measures seek to ensure compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Therefore, approval from the Institutional Review Board (IRB) will not be pursued as this information has already been deidentified for research use.

CHAPTER IV RESULTS

4.1 Results/Findings

Overall, there were 5,555 women diagnosed with breast cancer between the years 2018 and 2021 living in the state of South Carolina who met the inclusion criteria for the study. The table explains the cohort characteristics based upon the surgical procedure performed: BCS or mastectomy, and further describes the following demographical characteristics: age, race, Charlson Comorbidity Score, year of surgical procedure, location of surgical procedure, length of stay, geographic location, cost of procedure, and income status.

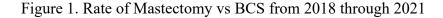
The sample population was divided into two groups based on the surgical procedure elected to treat breast cancer. There were 4,416 women living in South Carolina who had chosen to undergo a surgical mastectomy and 1,139 women who had elected breast conserving surgery as their primary treatment for breast cancer. Our inclusion criteria wanted to capture data for all women living in South Carolina between the ages of 40 and 85. However, we only found data on women aged 60 through 84 who met the study criteria.

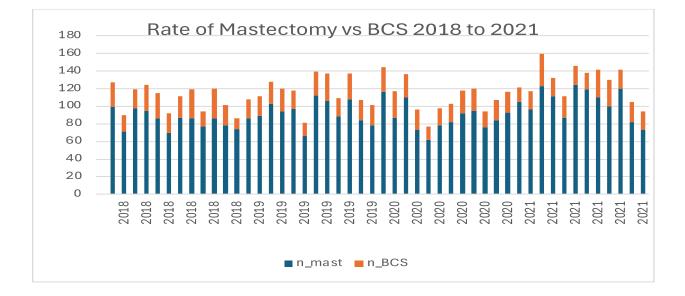
After analyzing the data, we found that women in higher age brackets were more likely to have had a mastectomy performed rather than breast conserving surgery (p = 0.0123) as their primary treatment for breast cancer. Breast conserving surgery appeared to be the top choice selected by younger women between the ages of 60 to 64, as women aged 70 to 74 were more likely to elect a mastectomy for their primary surgery. There were no racial differences in rates of women who chose to undergo a mastectomy or BCS (p = 0.922).

Characteristics	Breast Conserving Surgery n=1,139	Mastectomy n=4,416	p-value
Age:	7		0.0123
60 to 64	279 (24.5)	936 (21.2)	
65 to 69	286 (25.1)	1148 (26.0)	
70 to 74	275 (24.1)	1144 (25.9)	
75 to 79	177 (15.5)	799 (18.1)	
80 to 84	122 (10.7)	389 (8.8)	
Race:			0.0922
Black	290 (25.5)	993 (22.5)	
Hispanic	12 (1.1)	26 (0.6)	
Caucasian	817 (71.7)	3314 (75.0)	
Missing	2 (0.2)	12 (0.3)	
Other	18 (1.6)	71 (1.6)	
other	10 (1.0)	, 1 (1.0)	
Charlson Score	3.4 +/- 2.0	3.0 +/- 1.6	
			< 0.0001
(continuous)	2.0 [2.0-5.0]	2.0 [2.0-3.0]	<0.0001
Charlson Score			< 0.0001
(categorical)			~0.0001
2	662 (58.1)	2864 (64.9)	
3	125 (11.0)	571 (12.9)	
4	62 (5.4)	166 (3.8)	
4 5	26 (2.3)	64 (1.4)	
6		629 (14.2)	
	178 (15.6)		
7 8+	42 (3.7)	80 (1.8)	
	44 (3.9)	42 (1.0)	0.0045
Year of Surgery	200 (25 5)	1005 (00 0)	0.0845
2018	290 (25.5)	1005 (22.8)	
2019	284 (24.9)	1111 (25.2)	
2020	280 (24.6)	1050 (23.8)	
2021	285 (25.0)	1250 (28.3)	
Level Constraint			<0.0001
Inpatient Surgery	22((10.8)	(2(1,4))	< 0.0001
	226 (19.8)	62 (1.4)	
T - 1 - 6 C -	1.6.101		
Length of Stay	1.6 +/ 2.1	1.2 +/ 1.7	.0.0001
	1.0 [1.0 -1.0]	1.0 [1.0 - 1.0]	< 0.0001
Geographic Location			0.2229
	902 (79.4)	2522 (70.9)	0.3238
(RUCC 2013)	893 (78.4)	3523 (79.8)	
Metropolitan	145 (12.7)	492 (11.1)	
Urban Rural	101 (8.9)	401 (9.1)	
Social Vulnerability			0.2819
Index >= 90	233 (20.5)	841 (19.0)	0.2017
Index >= 90	255 (20.5)	041 (19.0)	
Total Charges	49,464 +/- 36,007	29,462 +/- 14,329	
	20 542 [20712 55125]	28 200 [20 0/4 25 051]	
	39,543 [29713-55125]	28,200 [20,064-35,951]	-0.0001
			< 0.0001
	0.5.1.0.0	051/00	
ACS GINI Index	0.5 +/- 0.0	0.5 +/ 0.0	
ACS GINI Index	0.5 + 7 - 0.0 0.5 [0.5 - 0.5]	$0.5 \neq 0.0$ 0.5 [0.4 - 0.5]	0.1721

Table 1. Characteristics of Study Population living in South Carolina

There was a difference in the findings based on the Charlson Comorbidity Index Score, those women with two or more comorbidities were more likely to have breast conservation surgery performed than surgical mastectomy (p = <0.0001). Women with fewer comorbid conditions frequently chose to have a mastectomy performed as their primary surgical treatment (64.9%; p = <0.0001). The data clearly showed that the number of mastectomy cases during the study period outweighed the number of breast conserving surgery cases as shown in Figure 1.





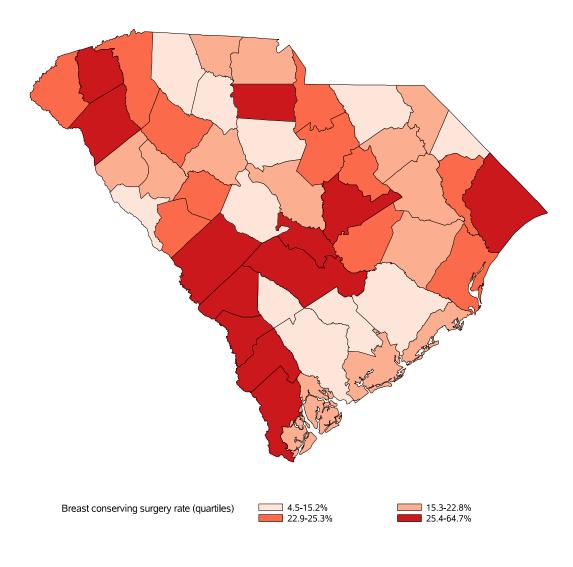
Surprisingly, the number of mastectomy cases was more than three times the number of breast conserving surgery cases recorded. Another interesting finding was the number of BCS cases occurring on an inpatient status was almost four times the number of mastectomy cases performed (19.8% vs. 1.4%, respectively)-which was a significant difference (p <0.0001). Further assessment of the data has revealed that a difference does not exist between mastectomy rates and BCS rates based on geographical location (p = 0.3238) as shown in Table I.

Unadjusted analysis of the charges for each surgical procedure revealed that marked difference were noted between the costs of each surgery. The unadjusted total charges for BCS (\$49,464) were more expensive than having a mastectomy (\$29,462) (p < 0.0001). An increased medical cost could be attributed to inpatient charges, repeat procedures, increased length of stay, or postoperative complications. The data revealed that income or socioeconomic status had no bearing on the impact of a woman electing a mastectomy or BCS according to the American College of Surgeons.

We investigated the odds of BCS based on the patient's geographic location {Metropolitan, Urban, Rural} using a logistic regression analysis, adjusting for inpatient versus outpatient, Charlson score, Age, Race, and whether a patient's Social Vulnerability Index was \geq 90. We evaluated model fit using the Hosmer-Lemeshow goodness of fit test, which showed good model fit (p = 0.8278). This analysis found no difference among the geographic locations (p = 0.0903); comparing urban vs metro (OR: 1.200, 95% CI: 0.967 vs. 1.489), and rural vs. urban (OR: 0.852, 95% CI: 0.836-1.258).

Figure 2: Depicts a heat map based on the occurrence of BCS performed in South Carolina broken down by county. There are four different color shades, each representing the number or "hotness" of the county according to the number of recorded BCS cases. The darkercolored counties are associated with an increased number of breast conservation cases with no relationship or connection to geographic location, urban, rural, or metropolitan.

Figure 2. Breast Conserving Surgery Rates



In summation, rurality or geographical location does not affect the types of surgical procedures performed to treat breast cancer. Other variables or factors, shown to be statistically significant: increasing age, the Charlson Comorbid Index, inpatient surgery, length of stay, and total charges may all impact a woman's choice in choosing her primary breast cancer surgery treatment.

CHAPTER 5 DISCUSSION

5.1 Discussion of Results

Understanding the potential impact that geographical location may have on an individual's ability to access and utilize quality medical care and services, specifically looking at mastectomy rates versus BCS rates among women diagnosed with BC was the primary objective of this project. Those living in rural communities often face additional barriers when attempting to access healthcare services and this researcher was interested in learning if any of those potential barriers had any impact on patient choice for breast cancer surgical care. Electing to have BCS, requires the woman to commit to at least six weeks of radiation therapy for full treatment. Geographically, women living in rural areas may not have access to local radiation treatment facilities and this could explain why these women choose to have a total mastectomy over BCS. Living in rural communities can contribute to longer traveling commutes to access healthcare systems in urban or metropolitan communities. Living in remote areas does not foster readily available access to healthcare systems which could contribute to the lack of adherence to guideline concordant care among rural residents.

Although the incidence of developing breast cancer increases with age this study did not capture any women younger than 64 who received breast cancer surgery. The study revealed that women of older age elected to undergo mastectomy more often than breast conservation surgery. This decision could be the result of current lifestyle choices or the woman not wanting to undergo multiple surgeries in the future. Another possible reason for choosing mastectomy over BCS could stem from a misconception that a mastectomy prevents the reoccurrence of cancer. Clinically, it is not possible to remove all subcutaneous breast tissue and the potential risk for breast cancer to return will always be present for either surgery. Many women may perceive that electing to have a total mastectomy will decrease their risk of cancer in the future.

This study was attempting to examine whether women living in rural counties throughout South Carolina experienced higher mastectomy rates versus breast conserving surgery rates when compared with women living in urban counties. However, we found no difference in the type of surgery performed based on the patient's geographical location-even after adjusting for important covariates.

The state of South Carolina is home to 17 Commission on Cancer (CoC) accredited hospitals focused on providing quality cancer programs and treatments to the communities they serve. Past research has shown that costs are an important factor when making healthcare decisions. Although this investigator was unaware if the women in the sample were aware of the cost difference before making a surgical decision, this study revealed that there was a twentythousand-dollar difference in cost between a total mastectomy and BCS. The differences in cost could be attributable to daily inpatient charges, postoperative complications, or the use of ancillary hospital services but this would require further examination.

With BCS being the preferred intervention for unilateral breast cancer disease, the data reports that the rates of mastectomy procedures performed in South Carolina are consistently higher than the rates of BCS. Unfortunately, this study revealed that there was a high proportion of women in South Carolina who elected to undergo a mastectomy instead of BCS (4,416 [79.5%] vs. 1,139 [20.5%]). Knowing this information will allow professional healthcare providers to modify their current practices based on the current standards of care set by the American Joint Commission on Cancer.

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5.2 Implications for Policy and Practice

Both surgical options for breast cancer treatment have advantages and disadvantages that become apparent to the patient and her medical/ surgical healthcare provider during the decisionmaking stage. As educated health professionals, we must educate the public and our U.S. Congressmen and Senators about the need to support long-term cancer surveillance programs and initiatives to maximize survivability from this deadly disease. Women electing for curative treatments of BC through surgery should be educated about the long-term effects of breast cancer treatments. Breast cancer survivors face several challenges post-surgery, for example, psychological changes, physical changes related to functioning post-mastectomy, and the potential for cardiac, renal, and neurocognitive dysfunction secondary to prescribed treatment modalities. The enactment of laws that require insurance providers to become fully engaged in their insured's care and educated on the long-term ramifications of breast cancer management to support the woman with monitoring, screening, and managing long-term medical effects and complications of chosen treatments and interventions.

5.3 Limitations

This study may have several limitations. The small sample size of 5, 555 women treated with BC over three years may make results not generalizable to other U. S. states. The sample population did not contain any data for women below the age of 64. This study did not account for the number of women who sought and received healthcare services in neighboring healthcare facilities across state lines. Most rural communities have large segments of poor, elderly, and minority populations, making these results less transferable to large metropolitan cities in Northeastern states. The data was collected from the South Carolina All-Payer Claims Database, this database may have housed data specific only to Medicaid recipients providing incomplete 34

data. The use of this database could have prevented data from other insurance carriers or providers from being included in the study population and could have impacted our analysis.

5.4 Future Research

To my knowledge, this is the first study that attempted to associate breast cancer surgical type to geographic location in South Carolina. Future research should be geared toward promoting the standard of care in breast cancer management. Quality care is provided through a multidimensional approach involving surgery, radiation therapy, chemotherapy, and hormone-targeted therapy in every geographical setting. Future research should focus on eliminating or minimizing potential long-term effects and/or consequences from breast cancer surgery. The efficient utilization of healthcare system personnel located in rural communities will further help eliminate the disparities seen in breast cancer care and management. Future research in rural communities could eliminate misconceptions associated with rural cancer care management; and promote equivalent quality medical and surgical care within these communities.

5.5 Conclusions

In conclusion, geographical location, whether metropolitan, urban, or rural was proven to not have a significant effect on the type of surgical procedures performed on women living in South Carolina diagnosed with breast cancer. Unfortunately, this study revealed that there was a high proportion of women in South Carolina who elected to undergo a mastectomy instead of BCS (4,416 [79.5%] vs. 1,139 [20.5%]). The argument of which surgical procedure is the best and which should be the gold standard of care resurfaces. One school of thought in medicine, practices utilization of BCS as the standard of care for women with unilateral, noninvasive, nonmetastatic BC, unless contraindicated, while other healthcare professionals emphasize that the standard of care is providing an open patient-to-physician relationship that allows a discussion of all available, appropriate options, discussing the pros and cons of each treatment and allowing the patient to make a fully informed decision as to which treatment is best for them. Efforts to promote quality breast cancer care will include educating the public on the best surgical options offered to eradicate the disease. The push for expert healthcare professionals living and working in rural communities to increase healthcare access for all has become essential.

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Appendix A.

International Classification of Diseases (ICD)10 Codes for Malignant Neoplasms of the Breast

ICD-10-CM CATEGORY	ICD-10-CM TERM	
C50.01	Malignant neoplasm of nipple and areola, female breast	
C50.11	Malignant neoplasm of central portion of breast, female breast	
C50.21	Malignant neoplasm of upper-inner quadrant of female breast	
C50.31	Malignant neoplasm of lower inner quadrant of female breast	
C50.41	Malignant neoplasm of upper outer quadrant of female breast	
C50.51	Malignant neoplasm of lower outer quadrant of female breast	
C50.61	Malignant neoplasm of axillary tail of female breast	
C50.81	Malignant neoplasm of overlapping sites of female breast	
C50.91	Malignant neoplasm of breast of unspecified site of female breast (includes Triple Negative Breast Cancer)	
Z92.3	Personal history of irradiation	
Z17.0	Estrogen receptor positive status (ER+)	
Z17.1	Estrogen receptor negative status (ER-)	
Z15.01	HER 2+ receptor status (HER-2 +)	

Appendix B.

International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM)

Codes Used for Classification of Diagnosis and Procedures

Breast Cancer Procedure	Procedure Category	ICD-9-CM
Mastectomy *Unilateral Simple Mastectomy	Unilateral Simple Mastectomy - (NOS) -Complete	85.41
	Unilateral Extended Simple Mastectomy -Extended Simple Mastectomy NOS -Modified Radical Mastectomy -Simple Mastectomy with excision of regional lymph nodes (RLN)	85.43
	Unilateral Radical Mastectomy -Excision of breast, pectoral muscles, and RLN -Radical mastectomy NOS	85.45
	Unilateral Extended Radical Mastectomy -Excision of breast, muscles, and RLN -Extended Radical Mastectomy	85.47
Bilateral Mastectomy	Bilateral Simple Mastectomy -Bilateral complete mastectomy	85.42
	Bilateral Extended Simple Mastectomy	85.44
	Bilateral Radical Mastectomy	85.46
	Bilateral Extended Radical Mastectomy	85.48
Breast Conserving Surgery -Partial mastectomy	Excision or destruction of breast tissue	85.20
-Quadrantectomy -Segmental mastectomy	Local excision of lesion of breast	85.21
Segmental masterionity	Quadrant resection of the breast	85.22
	Subtotal mastectomy	85.23 85.25

Abbreviations: NOS (not otherwise specified) these breast cancers do not have specific differentiating features,

RLN (regional lymph nodes) includes axillary, clavicular, supraclavicular nodes.

Appendix C.

Classification of Breast Cancer by Stages, Description, and Available Treatments

Stage	Description	Treatment
Noninvasive:		
-Stage 0 (in situ)	-Precancerous lesions with no local or distant metastasis -Known as Ductal Carcinoma (DCIS) or Lobular Carcinoma in	Breast Conserving Surgery Mastectomy
	Situ (LCIS) -The breast cancer is contained	Radiation
	within the breast ducts or lobules -No evidence of cancer invading the surrounding normal tissue	Hormone/ Endocrine Therapy
Invasive:		
Stage I: - IA	-No evidence of cancer spreading outside of the breast	Endocrine therapy
-IB	-The cancer is confined to the breast and has not reached the	Immunotherapy
	lymph nodes -Tumor size less than 2 cm	Chemotherapy (NAC or PAC)
	-Although the tumor is confined to	Radiotherapy
Stage II:	the breast, it has spread to the axillary lymph nodes	Lumpectomy
- IIA - II	-Tumor size > 2 but less than 5 cm	Mastectomy
Stage III - IIIA - IIIB	-Tumor size > 5cm -Locally advanced disease -Breast cancers are large tumors or locally advanced at the time of diagnosis -Breast cancer has metastasized to lymph nodes, chest wall, or to the skin of the breast	
Metastatic	Skill of the breast	
Stage 4	-Advanced and metastatic stage of breast cancer -Tumor of any size with spread to other major organs (brain, liver, lungs, bones, etc.)	Chemotherapy

Abbreviations: NAC (neoadjuvant chemotherapy), PAC (post adjuvant chemotherapy) the administration of

chemotherapy before or after surgical treatment; b radiotherapy, the use of high-energy or ionizing radiation to affect

DNA of cancer cells; c. chemotherapy, the use of cytotoxic agents to kill cancer cells

Appendix D.

Current Procedural Terminology (CPT) codes for Breast Surgery and their descriptions.

19301	Mastectomy, partial (i.e., lumpectomy, quadrantectomy, segmentectomy) with oncologic resection and excision of surrounding tissue for margins
19302	Mastectomy, partial (i.e. lumpectomy, quadrantectomy, segmentectomy) with axillary lymphadenectomy
19303	Mastectomy, simple, complete, can include nipple sparing or skin sparing techniques
19304	Mastectomy, subcutaneous, preserves the skin, nipple and areola
19305	Mastectomy, radical, including pectoral muscles, axillary lymph nodes
19306	Mastectomy, radical, includes removal of the entire breast, nipples, skin around the nipples, pectoral muscles, axillary and internal mammary lymph nodes
19307	Mastectomy, modified radical, including the entire breast, pectoral muscle, axillary and internal mammary lymph nodes

Maintained @American Medical Association (AMA) Current Procedural Terminology

Name of County	County of	Mastectomy	BCS Cases by	Rate of BCS
	Residence	Cases by County	County	(2018-2021)
Abbeville	1	22	***	0.21429
Aiken	2	36	45	0.55556
Allendale	3	***	***	0.6
Anderson	4	182	70	0.27778
Bamberg	5	21	***	0.04545
Barnwell	6	***	***	0.64706
Beaufort	7	162	35	0.17766
Berkeley	8	135	21	0.13462
Calhoun	9	***	***	0.54545
Charleston	10	332	73	0.18025
Cherokee	11	68	18	0.2093
Chester	12	***	***	0.33333
Chesterfield	13	44	***	0.10204
Claredon	14	49	15	0.23438
Colleton	15	23	***	0.11538
Darlington	16	76	19	0.2
Dillon	17	38	***	0.07317
Dorchester	18	115	***	0.06504
Edgefield	19	***	***	0.25
Fairfield	20	19	***	0.09524
Florence	21	179	46	0.20444
Georgetown	22	168	50	0.22936
Greenville	23	484	145	0.23052
Greenwood	24	70	15	0.17647
Hampton	25	17	***	0.34615
Horry	26	319	113	0.26157
Jasper	27	11	***	0.3125
Kershaw	28	59	20	0.25316
Lancaster	29	13	***	0.23529
Laurens	30	59	19	0.24359
Lee	31	***	***	0.25
Lexington	32	356	40	0.10101
Marion	34	37	11	0.22917
Marlboro	35	13	***	0.1875
McCormick	33	31	***	0.13889
Newberry	36	49	***	0.15517
Oconee	37	95	30	0.24
Orangeburg	38	91	32	0.26016
Pickens	39	106	43	0.28859
Richland	40	294	57	0.16239

Appendix E. Breast Surgical Procedures reported by county in South Carolina (2018-2021)

Name of County	County of	Mastectomy	BCS Cases	Rate of BCS
	Residence	Cases		(2018-20210
Saluda	41	16	***	0.2381
Spartanburg	42	420	74	0.1498
Sumter	43	47	19	0.28788
Union	44	50	***	0.15254
Williamsburg	45	38	11	0.22449
York	46	32	***	0.2

*** denotes cell size suppressed due to small cell size, in accordance with the data use

agreement

Appendix F.

- AJCC: American Joint Committee on Cancer
- APCD: All-Payer Claims Database

BC: Breast Cancer

BCS: Breast Conserving Surgery/ Breast Conservation Surgery

BCT: Breast Conservation Therapy

BMI: Body Mass Index

DHEC: South Carolina Department of Health and Environmental Control

ER: Estrogen Receptor

HER2: Human Epidermal Receptor Factor 2

HIPAA: Health Insurance Portability and Accountability Act of 1996

ICD: International Classification of Diseases

PHI: Protected Health Information

PR: Progesterone Receptor

SBE: Self Breast Examination

TNBC: Triple Negative Breast Cancer

U.S.: United States