An Analyses of Outcomes and Characteristics of Patients undergoing Elective Procedures for Managing Risk or Presence of Breast Cancer

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ABSTRACT

BACKGROUND: Breast cancer is the most commonly diagnosed female cancer in the United States. According to the American Cancer Society in 2020 there will be an estimated 276,480 new cases of invasive breast cancer diagnosed in the United States. Surgery continues to be the gold standard for treatment. While breast conserving surgery has been widely accepted, many patients elect mastectomy. The objective of this study was to examine hospital characteristics of mastectomy patients to determine what factors impact length of stay, total charges and in-patient mortality.

METHODS: The objective of this study was to analyze the frequency of mastectomy, whether for risk reduction or the presence of disease. This study utilized the National Inpatient Sample (NIS) database for years 2008 to 2011 to examine patient demographic characteristics such as age, race, insurance type and income. SPSS statistical analysis version22 was utilized for analysis, with p values less than .05 considered significant. Linear regression, Logistic Regression, A NOVA and Chi-Square were used to determine significant predictors of study outcomes

RESULTS: Between 2008 and 2011, 55,781 female patients underwent mastectomy with 76.7% electing unilateral mastectomy. Immediate breast reconstruction occurred in 38.6% of patients. The highest incidence of mastectomy occurred in White and Asian women. The total number of discharges revealed privately insured White and Asian women had the highest discharge each year. A further analysis regarding income revealed Whites and Asians also had the highest income. Length of stay remained

consistent from 2008 through 2011. Mortality was insignificant among the mastectomy population with Blacks seen to have the highest percentage of in-hospital mortality. Fluid and electrolyte disorders were found to be the highest predictors of mortality. Overall totals costs were on a rising trend and consistent with type of mastectomy.

CONCLUSION: Among hospital inpatients electing mastectomy, there were racial differences that occurred in treatment and outcomes. This study highlighted hospitalization characteristics related to female mastectomy admissions in the United States between 2008 and 2011. Racial disparities in treatment and outcomes highlight areas where efforts may be focused to improve survival among specific population groups. Future research should be targeted on identifying specific causes of racial differences in patients electing mastectomy and outcomes related thereto. This study validates the importance of health education to improve health awareness. Policies promoting early childhood health education may provide the necessary knowledge and life skills to aid in navigating access to resources to promote better health.

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CHAPTER I
INTRODUCTION TO THE STUDY

1.1 Background and History of Mastectomy

Breast Cancer has been a known disease for more than 3600 years and was at one time considered incurable. As such, a diagnosis of breast cancer was left without treatment for almost 1700 years. [1] During the renaissance period there were barbaric and often mutilating attempts to treat breast cancer. Early attempts to treat breast cancer made use of the "escharotomy method" where the surgeon used a hot poker making repeated incisions to burn the breast off the chest wall. In addition to this maiming treatment, the guillotine was also used for removal of the cancerous breast. [2] These mutilating attempts failed in providing management of the disease and often resulted in increased infection and in high mortality.

During the late 1800s and early 1900s, the use of mastectomy was still considered an unacceptable procedure, offering no survival benefit. It was not until a surgeon at Johns Hopkins Hospital in Baltimore, Maryland named William Stewart Halsted began to theorize about breast cancer treatment. Halsted focused his research on understanding the path and spread of disease with the objective of preventing metastases. [3] Through his research, he developed a procedure for treating breast cancer known as the radical mastectomy. [4]

1.2 Radical Mastectomy

Anesthesia was introduced in the mid 1800's. Prior to that time period, surgeons could only offer patients opium or alcohol as a method of pain reduction or an even more archaic option where the patient was provided a bullet to clench between their teeth to combat the pain of surgery. It was not until October 16, 1846, that the first surgical procedure using anesthesia was documented. [5] During this time period, William Halsted began to describe his radical breast procedure. Halsted theorized that the spread of breast cancer was local, with the early stages of disease attacking only the surrounding tissue before moving to the ducts and lymph nodes. Once the cancer had invaded the lymph nodes, the cells became trapped before pervading the blood vessels which would ultimately carry the cancer to other areas of the body.[6]

Halsted's procedure, which entailed removing breast tissue, overlying skin, chest muscles, and lymph nodes in the armpit was named the "Radical Mastectomy" also known as the "Halsted Procedure." [7]This procedure was offering breast cancer patients a safer option with low mortality and low percentage of cancer recurrence. Figure 1 depicts a surgical comparison of local breast cancer recurrence from years 1882 through 1895 with the Halsted Procedure having the lowest percentage of local recurrence. Despite the deformity of this radical procedure, Halsted believed it was the only way to mitigate against recurrence.[8] The radical mastectomy remained the standard treatment

for breast cancer for more than 70 years.

Surgeon	Years	n	Local recurrence (%)
Bergmann	1882–1887	114	51–60
Billroth	1867–1876	170	82
Czerny	1877–1886	102	62
Fischer	1871–1878	147	75
Gussenbauer	1878–1886	151	64
König	1875–1885	152	58–62
Küster	1871–1885	228	59
Lücke	1881–1890	110	60
Volkmann	1874–1878	131	59
Halsted	1890–1895	50	6

Figure 1 Results of mastectomies for breast cancer by surgeon 1867-1890 (Osborne, MP. Lancet Oncol 2007 Mar;8(3):256-65)

1.3. Modification of the Radical Mastectomy

In the 1940's a less radical procedure emerged. The new procedure modified Halsted's radical mastectomy, allowing for preservation of the pectoralis major. Within a short period of time, the technique of sparing both pectoral muscles emerged.[9] The modified radical mastectomy became the standard of care for treating breast cancer until 1970.[10]

1.4 The Shift from the Radical Mastectomy

In the 1970s the treatment goal for the management of breast cancer changed direction, and with that came a surgical change. The extreme radical procedure was slowly replaced by a less invasive and more cosmetically focused outcome without affecting prognosis or survival. During the 1970's, many randomized clinical trials were conducted offering comparisons to mastectomy. It was during this time that mammography was introduced. The use of mammography allowed for earlier detection of smaller lesions. In addition to mammography, radiotherapy was also introduced, providing a new outlook on the management of breast cancer.[11] It also was during this time that Bernard Fisher, a innovator in breast cancer research, developed a new theory

concerning breast cancer. Fisher believed that disease was systemic and that microscopic metastases were present early on in most patients and that surgery had very little impact on overall survival. [12] The results of clinical trials revealed that breast-conserving surgery in combination with radiation therapy were as effective as mastectomy in management of breast cancer. In 1990, Fisher's research led to realization that mastectomy may no longer be necessary for most patients faced with a diagnosis of breast cancer.[13]

1.5 Women's Health and Cancer Rights Act and breast reconstruction

The Women's Health and Caner Rights Act (WHCRA) was enacted in 1998. WHCRA offers protection to women who elect breast reconstruction after mastectomy. The WHCA applies to all stages of reconstruction. The WHCRA does not mandate minimum length of hospital stay in connection with reconstruction. The law applies to group health plans provided by an employer or union as well as individual health plans not employment based. Under the WHCRA coverage must be provided for the following:[14]

- All stages of reconstruction on the effected breast
- Surgery including reconstruction on the unaffected breast to improve overall cosmetic appearance
- Prostheses and surgical complication treatment including lymphedema

1.6 Cosmetic advances and Skin and Nipple Sparing Mastectomy

In 1950, the silicone implant was introduced. The silicone implants were used after mastectomy to aid in returning the breast to its natural form. During this time, reconstruction was only used post-mastectomy for non-malignant disease. Reconstruction was not used as a surgical technique for malignant disease until 1991.[15]

In 1991, a new technique called the skin-sparing mastectomy was defined by Toth and Lappert. This new technique allowed for removal of the breast tissue, preserving much of the overlying skin as possible leading to an improved cosmetic outcome. [16] Skin-sparing mastectomies were performed for patients with early stage breast cancer, such as ductal carcinoma in situ and other cases where the cancer had not advanced.

Additionally, smoking status was also assessed in patients considered for a skin-sparing mastectomy. Nicotine is a vasoconstrictor that affects the skin and overall healing. Nicotine influences capillary flow thereby making this procedure preferred for patients who are a non-smokers.

Nipple-sparing mastectomies (NSM) followed the skin-sparing technique. There is oncologic concern regarding removal of the nipple and areola complex as part of a therapeutic mastectomy due to concern of hidden cancer cells in the nipple-areola complex. The NSM is not fully accepted by all surgeons due to the concern for local or regional recurrence. NSM is widely accepted for patients electing prophylactic mastectomy. Advancements in mastectomy continued through the Twentieth Century where surgical improvements continued to focus on improving cosmetic outcomes.[17][18]

1.7 Importance of the study

In the United States, Breast cancer is the most common cancer in women. In 2020, the American Cancer Society estimates there will be approximately 276,480 new cases of invasive breast cancer in the United States alone with an estimated 42,170 deaths[19]. Women with a diagnosis of breast cancer are often faced with a difficult decision; whether to have surgery on the cancer free, contralateral breast. Additionally, women

who are at an increased risk of breast cancer may be faced with the same difficult decision.

A study has not been conducted measuring length of stay (LOS), total charges and mortality for hospital inpatients electing mastectomy whether for risk management or disease presence. This study has revealed the findings and results using a national inpatient database consisting of 1040 hospitals throughout the United States. The uniqueness of this study examined parameters such as demographics factors and comorbidities related to patients electing mastectomy. Additionally, the study examined socioeconomic background of inpatients across the races providing a unique insight into how race and income level may impact decision making.

The importance of this research is to provide further understanding of inpatient cost of care for patients electing mastectomy utilizing the Healthcare Cost and Utilization Project (HCUP), National Inpatient Sample database. Nationwide databases are suited to answer these questions because of their large diverse patient populations. Given the lack of knowledge and the increasing rate of mastectomy, this study aims to identify socioeconomic differences in charges when undergoing mastectomy in response to a breast cancer diagnosis or for management of risk. Additionally, this research will examine hospital factors that lead to increased charges in women undergoing mastectomy.

1.8 Research Questions and Hypothesis

1. What clinical factors, such as type of mastectomy (bilateral/unilateral) affect the total charges?
2. What clinical factors, such as number and types of comorbidities affect length the total charges?
3. Whether prophylactic bilateral mastectomy differs with race, age or economic status?

4. What clinical factors, such as type of mastectomy (bilateral/unilateral) affect disposition of patient?
5. Whether there are socioeconomic differences and total charges?
6. Whether there are socioeconomic differences with length of stay?
7. Whether there are differences in total charges across the various regions of the United States?
8. Whether there are differences in total cost across hospital locations?
9. Whether there are differences in length of stay within insurance type: Medicare, Medicaid, private insurance, uninsured?
10. What clinical factors, such as type of comorbidity affect mortality?

1.9 Research Hypothesis

Hypothesis 1: There are statistically significant associations between type of mastectomy and total cost.

Null Hypothesis: H0 = H1:

Alternative Hypothesis: H0 ≠ H1

Hypothesis 2: There are statistically significant association between type of comorbidities and total cost.

Null Hypothesis: H0 = H1

Alternative Hypothesis: H0 ≠ H1

Hypothesis 3: There are statistically significant associations between prophylactic bilateral mastectomy (PBM) and race, age or economic status.

Null Hypothesis: H0 = H1

Alternative Hypothesis: H0 ≠ H1

Hypothesis 4: There are statistically significant associations between type of mastectomy and disposition of patient.

Null Hypothesis: H0 = H1

Alternative Hypothesis: H0 ≠ H1

Hypothesis 5: There are statistically significant differences in total cost of mastectomy patients and race, age, or economic status.

Null Hypothesis: $H0 = H1$

Alternative Hypothesis: $H0 \neq H1$

Hypothesis 6: There are statistically significant differences in length of stay of mastectomy patients and race, age, or economic status.

Null Hypothesis: $H0 = H1$

Alternative Hypothesis: $H0 \neq H1$

Hypothesis 7: There are statistically significant differences in total cost of mastectomy patients and the various regions of the United States.

Null Hypothesis: $H0 = H1$

Alternative Hypothesis: $H0 \neq H1$

Hypothesis 8: There are statistically significant differences in total cost of mastectomy patients across the different types of hospital location.

Null Hypothesis: $H0 = H1$

Alternative Hypothesis: $H0 \neq H1$

Hypothesis 9: There are statistically significant differences in length of stay of mastectomy patients across the different types of payers; Medicare, Medicaid, private, and self-pay.

Null Hypothesis: $H0 = H1$

Alternative Hypothesis: $H0 \neq H1$

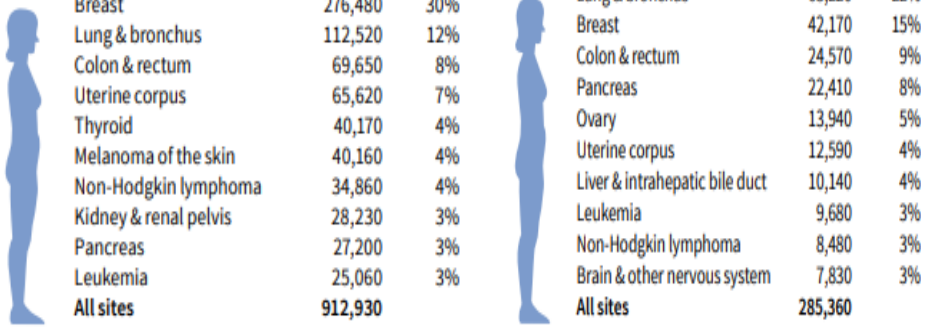
Hypothesis 10: There are statistically significant associations between type of comorbidity and mortality.

Null Hypothesis: $H0 = H1$

Alternative Hypothesis: $H0 \neq H1$

1.10 Statement of the Problem

In the United States, Breast cancer is the most common cancer in women. In 2020, the American Cancer Society estimates there will be approximately 276,480 new cases of invasive breast cancer in the United States alone with an estimated 42,170 deaths[20]. The Agency for Healthcare research and Quality (AHRQ) estimates that in 2015, the direct medical costs for cancer totaled $80.2 billion.



Female		
Breast	276,480	30%
Lung & bronchus	112,520	12%
Colon & rectum	69,650	8%
Uterine corpus	65,620	7%
Thyroid	40,170	4%
Melanoma of the skin	40,160	4%
Non-Hodgkin lymphoma	34,860	4%
Kidney & renal pelvis	28,230	3%
Pancreas	27,200	3%
Leukemia	25,060	3%
All sites	**912,930**	

Female		
Lung & bronchus	63,220	22%
Breast	42,170	15%
Colon & rectum	24,570	9%
Pancreas	22,410	8%
Ovary	13,940	5%
Uterine corpus	12,590	4%
Liver & intrahepatic bile duct	10,140	4%
Leukemia	9,680	3%
Non-Hodgkin lymphoma	8,480	3%
Brain & other nervous system	7,830	3%
All sites	**285,360**	

Figure 2. 2020, American Cancer Society, Inc., Surveillance Research

Surgery continues to be the gold standard treatment for early breast cancer. Although breast-conserving therapy has been widely accepted by many, some patients elect mastectomy due to disease factors or personal preference. Women at an increased risk of breast cancer, such as those with a strong family history, or women at high risk such as those with inherited mutations in the BRCA1 or BRCA2 genes have led elected prophylactic bilateral mastectomy. Advances in breast reconstruction techniques have expanded the options for women electing mastectomy. In the 1980's, the results of a large randomized clinical trial of surgical treatment alternatives for early stage breast cancer found that women who were treated with lumpectomy followed by a course of radiation were as likely to survive the disease as women who had mastectomy. [21] The

lumpectomy procedure was significantly less scarring and eliminated the need for plastic surgery. Unlike most diseases, breast cancer, particularly at an early stage is considered to have two medical treatment options: lumpectomy followed by radiation or mastectomy. [22] In the past two decades, the number of women who have chosen to remove both breasts after facing a cancer diagnosis in one breast has increased.[23]

There are limited studies that have examined drivers of increased hospital charges post mastectomy. The research identified focused on patients with unilateral breast cancer who underwent unilateral mastectomy in conjunction with contralateral prophylactic mastectomy. A 2017 study conducted by Bucknor et al., revealed patients undergoing contralateral mastectomy incurred greater charges if they were African American or Hispanic, or who had diabetes, obesity, increased complications, greater household income or longer length of stay. A decrease in charges was noted patients over 60. This study did not include patients without a history of breast cancer undergoing prophylactic bilateral mastectomy and cost variations related thereto.

The aim of this analysis was to include all patients undergoing mastectomy, regardless of disease presence, outlining the factors such as length of stay, mortality, age, race and insurance type and their effects on total charges.

1.11 Definition of terms

The definition of terms used in this study is illustrated in Table 1.

Table 1. Definition of terms

Term	Definition
Diagnosis	act of recognizing disease from its signs and symptoms
Mastectomy	surgical removal of one or both breasts
Prophylactic	intended to prevent disease
Mortality Rate	measure of number of deaths in population
Bilateral	two-sided
Unilateral	one-sided
Ipsilateral	occuring on the same side of the body
Contralateral	relating to or denoting the side of the body opposite to that on which a particular structure or condition occurs
Lymph Node	kidney shaped organ in the lymphatic system
Lumpectomy	surgical removal of a discrete portion or "lump" of breast tissue
Tamoxifen	medication used to prevent breast cancer
Breast reconstruction	takes place soon after mastectomy to recreate the breast
Tissue Expander	device used after mastectomy to allow the body to grow extra skin for use in reconstructing the breast
Chemoprevention	to lower a person's risk of developing cancer
Proliferation	how quickly a caneer cell copies DNA
Breast Neoplasm	benign proliferations to high risk lesions
Latissimus dorsi myocutaeous flap	oval flap of skin, fat and blood vessels from the latisimus dorsi muscle used to reconstruct the bresat
Traverse rectus abdominis myocutaneous flap (TRAM)	a flap of skin from the transverse rectus abdominus muscle, fat and all or part of the underlying rectus abdominus are used to reconstruct the breast
Deep inferior epigastric artery performator flap (DIEP)	skin, fat and blood vessels are cut from the wall of the lower belly to reconstruct the breast
Superior inferior epigatric artery performator flap (SIEA)	skin, fat and blood vessels are cut from the wall of the lower belly to reconstruct the breast - does not require blood vessels going through and around abdominal muscles
Gluteal artery performator flap (GAP)	skin, fat and blood vessels are cut from upper buttocks to reconstruct the breast

1.12 Importance of the study

Breast cancer is the most common malignancy in women. Advances in early detection as well as treatment have resulted in improved outcomes with nearly 90% surviving at least 5 years. [24]Women electing mastectomy whether to manage risk or due to the presence of breast cancer face a difficult decision. In 2020 the American Cancer Society

estimates that there will be an estimate 276,480 new cases of invasive breast cancer diagnosed in women in the United States. Women with unilateral breast cancer may consider contralateral risk-reducing surgery if they have a genetic pre-disposition or a strong family history of breast cancer. Women with genetic mutations in the BRCA gene, woman with biomarkers of increased risk or women with strong family history, may elect prophylactic bilateral mastectomy to reduce the risk of developing breast cancer. A study has not been conducted to highlight socioeconomic factors and financial impact of hospital charges related length of stay, total charges and mortality in patients electing unilateral or bilateral mastectomy with or without the presence of breast cancer.

CHAPTER II

LITERATURE REVIEW

2.1 Introduction

Breast cancer is the most commonly diagnosed female cancer in the United States. Family history is important in defining risk for future cancers, as women with one first degree relative with breast cancer have a two times greater chance of developing breast cancer. [25] Despite the alarming incidence of this disease, most women are not destined to ever experience a breast cancer diagnosis. Surgery continues to be the gold standard of treatment for early stage breast cancers. Advances in early detection as well as treatment have resulted in improved outcomes with nearly 90% of patients surviving at least five years. [26]Although breast-conserving therapy has been commonly accepted, many patients elect for mastectomy due to disease related factors or personal preference.

2.2 Risk factors and Breast Cancer

Breast cancer is the most commonly diagnosed cancer in women around the age of menopause. Cancer begins to grow when the cell's DNA is damaged. The scientific understanding as to why the DNA becomes damaged is still not known. There are certain risk factors that are associated with breast cancer. Some risk factors can be avoided, others cannot. The risk factors that cannot be changes are:[27]

1. Age. A woman's risk of breast cancer increases with age with more breast cancers being diagnosed after age 50.
2. Genetic mutations. Gene mutations that are inherited such as, BRCA1 and BRCA2 increase a woman's risk for the development of breast and ovarian cancer.

3. Dense breast tissue. Dense breasts have more connective tissue and less fatty tissue which can make breast cancer surveillance more difficult. Women with dense breast tissue have an increased risk of breast cancer.
4. Personal history of breast cancer or biomarkers of increased risk. Women with a history of breast cancer have a higher risk of breast cancer recurrence. Non-cancerous breast diseases such as lobular carcinoma in situ and atypical hyperplasia are biological markers that increase one's risk.
5. Family history of breast cancer. A woman with mother, sister, or daughter who have had breast cancer is at higher risk.
6. Previous treatment with radiation. A woman who has had treatment with radiation to the breast(s) or chest before the age of 30 has an increased risk for the development of breast cancer
7. Women to took diethylstilbestrol (DES). From 1940 through 1971 many pregnant women were given DES to prevent miscarriage. These women have a higher risk for the development of breast cancer. If a mother took DES while pregnant, her offspring also have an increased risk for the development of breast cancer.

2.3 Breast Cancer and age

According to the National Breast Cancer Foundation, two out of every three women diagnosed with invasive cancer are greater than 55 years of age with a median age at diagnosis at 61 as shown in Figure 3. The median age is 58 for African American women and 61 for White women. The median age of breast cancer death is 69 for White women and 62 for African American women.[28]

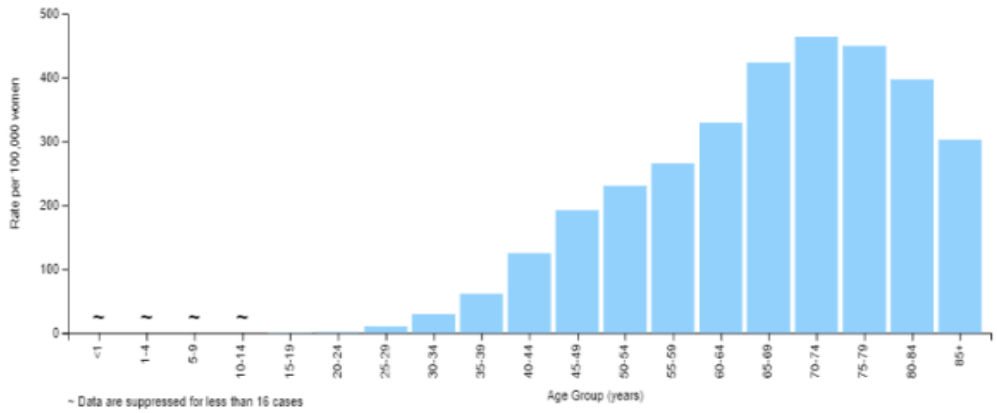


Figure 3 CDC Rate of New Cancers by age (2017)

2.4 Breast cancer and race

While cancer impacts women of all ages, races and ethnicities, it does not always affect them in the same way. Genetics, environment and hormones can impact risk. In Figures 4 and 5 below, the Centers for Disease Control and Prevention 2019 cancer statistics reveal White and Black women develop breast cancer at about the same rate, however, over the last 20 years, notwithstanding a drop-in mortality rates, there has been an increase in breast cancer in African American women. African American women have a 31% breast cancer mortality rate. This mortality rate is the highest of all racial groups.[29]

Asian Americans immigrants have lower rates of breast cancer than those born in the United States. A study conducted by Brittany N. Morey, PhD, et al. examined Asian American women living in the San Francisco Bay Area. The study compared three Asian American Groups: Those born in the United States, immigrants who resided in the United States at least 50% or more of their life and immigrants who lived less than 50% of their life in the United States. The results of this study revealed immigrant Asia American

women, whether living in the United States 50% of their life or less, had a three times higher risk of breast cancer than those born in the United States. [30]

A study conducted by Scarlett Lin Gomez, PhD and colleagues from Stanford Cancer Institute and the Cancer Prevention Institute of California from 1988 through 2013, reported the rate of breast cancer in different Asian American ethnicities. The study revealed that in the past 15 years, breast cancer rates have either remained the same or decreased in most populations. The twenty-six-year analysis showed breast cancer rates for Asian Americas are increasing. The authors of this study examined breast cancer trends from seven Asian ethic groups (Chinese, Japanese, Korean, Filipino, Vietnamese, South Asian and Southeast Asians). The data was then compared to the non-Hispanic White population. The results revealed breast cancer rates for Asian Americans are increasing as compared to non-Hispanic Whites. The factors contributing to this increase are not yet known.[31]

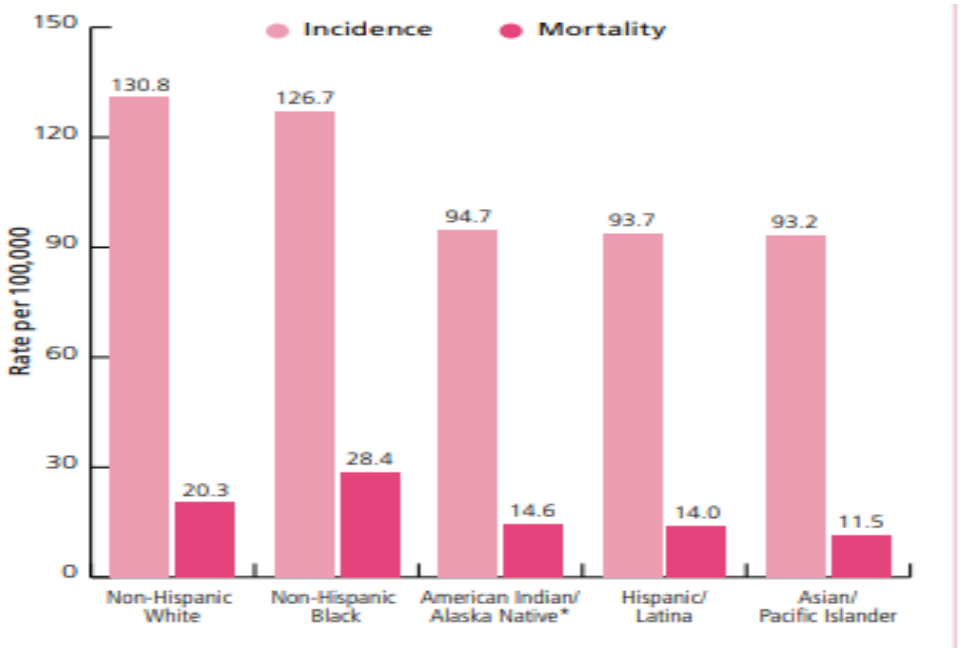


Figure 4 Center for Disease Control and Prevention

2019 incidence and mortality rates

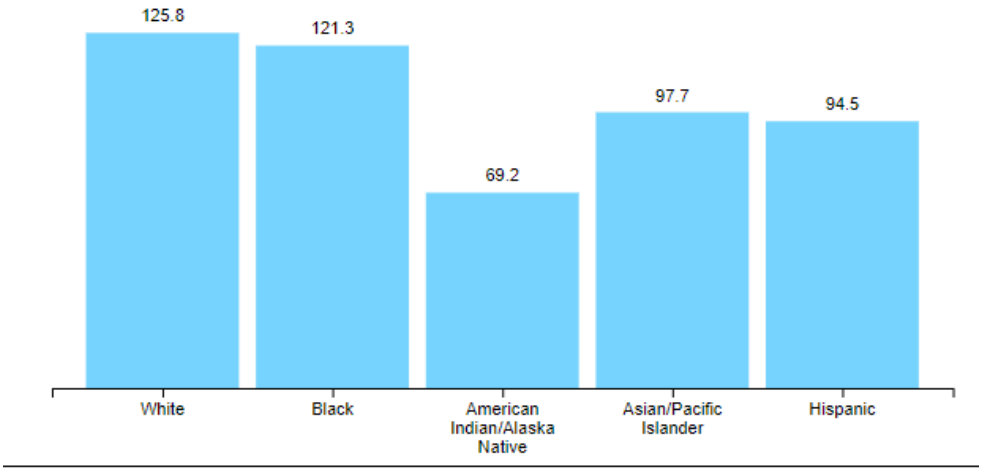


Figure 5 Center for Disease Control and National Cancer Institute 2019 race statistics

2.5 Mastectomy and risk reduction

A woman who receives a diagnosis of breast cancer is faced with a wrath of emotion as well as the unfortunate time is of the essence regarding treatment. The decision on whether to undergo breast conserving surgery or mastectomy is difficult. Research has shown this decision is too often directed by the physician rather than the patient. [32]The factors that influence decision are complicated and proper patient education is integral to better guide patients though this challenging decision-making process. Despite data that still supports breast conserving surgery for some patients, a large percentage of these women still choose mastectomy. The identified factors that often influence treatment decision are, fear of recurrence and body image.[33]

In contrast to women facing a cancer diagnosis, there are also those whose decision making is based solely on reducing the risk of ever facing a breast cancer diagnosis. Whether driven by fear, family history, genetics or influence of a health professional, some women choose to reduce risk at all costs. The most common risk reducing surgery

is bilateral prophylactic mastectomy. Bilateral prophylactic mastectomy (BPM) has been shown to dramatically reduce the risk of breast cancer in women at high risk. [34] BPM can reduce the risk of developing cancer by up to 95%. [35] The greatest risk reduction occurs if BPM is performed prior to age 40.[36]

Research in women greater than 40 years of age found a number of predictors for choosing BPM: close family member's cancer death, strong family history of breast cancer, desire to live longer for family and heightened breast cancer risk reception.[37] Few studies have reported on BPM decision making in women less than 40 years of age.

2.5.1 Lobular Carcinoma in situ and mastectomy

Lobular Carcinoma in situ (LCIS) was first defined in 1919 by James Ewing as a "noninvasive proliferation of the lobules and terminal ducts of the breast."[38] It did not acquire the name LCIS until Frank Foote, M.D. and Fred Stewart, M.D. labeled the lesion as such.[39] LCIS is usually an incidental finding wherein a patient has suspicious breast lesions warranting further clinical evaluation. Defined as a marker of increased risk rather than a true pre-cursor, women diagnosed with LCIS have an 8 to 10-fold increased risk of developing breast cancer. [40] The risk of subsequent breast cancer increases after an LCIS diagnosis by approximately .5 to 1% per year but that number is attuned based on the age of diagnosis and whether the patient has a family history of breast cancer. [41] The total life-time risk of developing breast cancer is 30 to 35%. [42] This risk remains steady throughout a person's lifetime, therefore the risk of developing breast cancer is significantly impacted by the age at which a patient is diagnosed.[43] Because initially it was regarded and treated as a pre-cancer that would further develop into invasive cancer the standard treatment for a diagnosis of LCIS was mastectomy of the breast in which it

was found (ipsilateral). [44] Mastectomy remained the gold standard until such time as further research found that the risk of developing invasive breast cancer was much lower than previously projected. A 29-year longitudinal study (1980-2009) conducted by Tari A. King et al. revealed that a diagnosis of LCIS in one breast does not increase one's risk that invasive cancer would develop in the other non-affected breast. The findings of this study concluded that BPM was no longer recommended clinically for a diagnosis of LCIS.[45]

LCIS cannot be diagnosed through mammographic characteristics. It is typically diagnosed when a patient is undergoing a breast biopsy due to suspicious findings on a mammogram or other type of breast surveillance. Cases of LCIS are on the rise due to the increase in surveillance. From 1978 to 1998, a clinical finding of LCIS increased 300%.[46]

2.5.2 Mutation in the BRCA gene and mastectomy

BRCA mutations are rare in the general population occurring in an estimated 1 in 400 individuals, dependent on ethnicity, carry mutations in the BRCA1 or BRCA2. [47] The National Cancer Institute estimates a woman who inherits the BRCA1 mutation has a 55-65% risk of developing breast cancer and a 39% risk of developing ovarian cancer by age 70. Management options for women with BRCA mutations include close surveillance, chemo-preventative therapy such as tamoxifen or prophylactic surgery. A 2001 study conducted by Lynn C. Hartmann et al. examined the association between bilateral prophylactic mastectomy and breast cancer in women at high risk. The study concluded that prophylactic mastectomy is associated with a significant reduction in the incidence of breast cancer not only in women with family history of breast cancer but also in known BRCA1 and BRCA2 mutation carriers. [48]

2.5.3 Mastectomy and the celebrity effect

Prophylactic bilateral mastectomy has been proven to be an effective method in reducing the risk of breast cancer in women at high risk for the disease. A celebrity's public announcement regarding choice of treatment can have a strong influence on medical care. In 1987, Nancy Regan, wife of President Ronald Regan, decision to undergo mastectomy brought on much controversy. Figure 6 below shows the percentage of breast conserving surgery from 1983 through 1990 for women age 30 and older. From 1983 through 1985 there was a gradual increase in breast conserving surgery, followed by a stable period through the beginning of 1987. At the end of 1987 through the beginning of 1988, there was a rapid decline in the use of breast conserving surgery.[49]

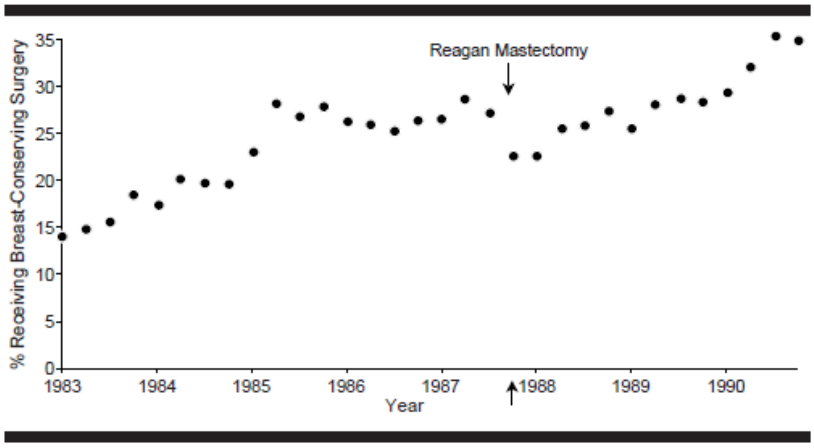


Figure 6 Percentage of use of breast-conserving surgery age 30 and older

On May 14, 2013, actress Angelina Jolie spoke openly about being a BRCA1 mutation carrier. Ms. Jolie revealed her decision to undergo prophylactic bilateral mastectomy with reconstruction. Angelina's story raised public awareness regarding genetic testing and resulted in noticeable increase in genetic testing as shown below in Figure 7.

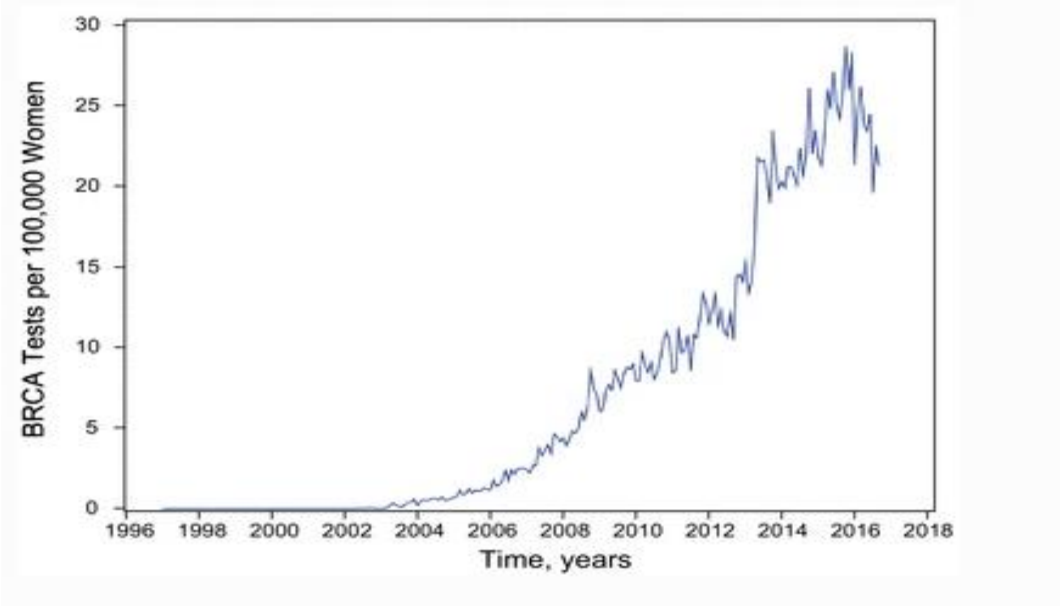


Figure 7 Incidence rates of BRCA testing from 1996 through 2018 (MarketScan database)

In addition to an increase in BRCA testing, there was also an increase in mastectomies for women who underwent BRCA testing as shown below in Figure 8.[50]

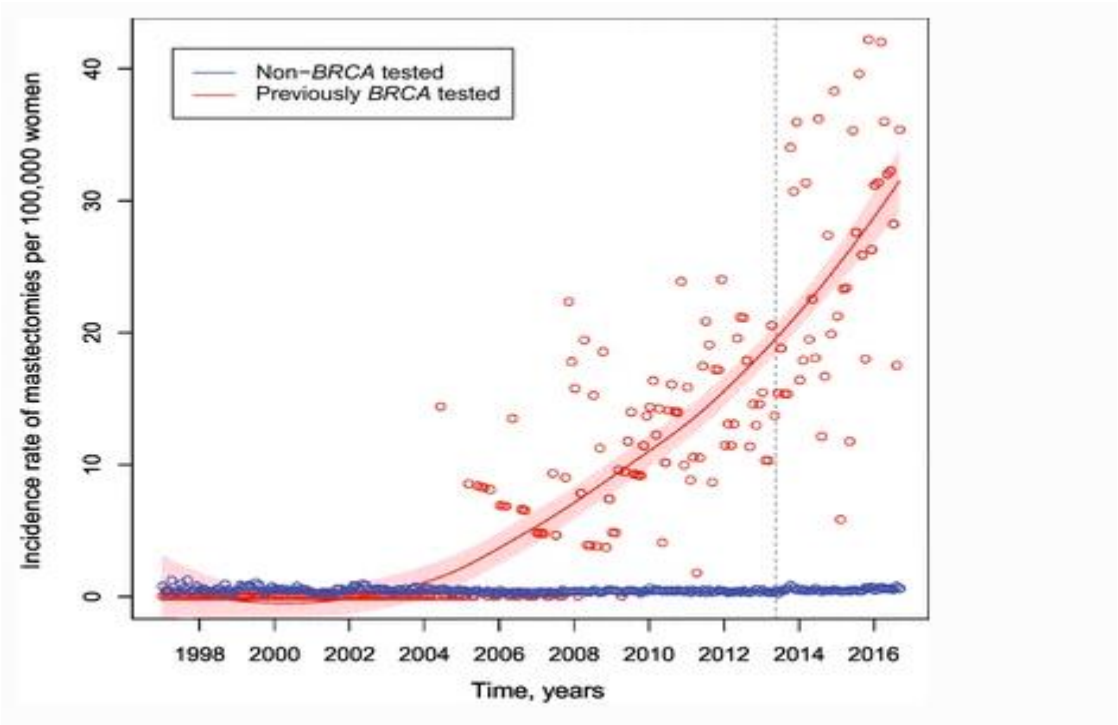


Figure 8 Incidence in rate of mastectomies from 1998 through 2016 (MarketScan database)

2.6 Mastectomy and early stage breast cancer

A woman who receives a diagnosis of breast cancer is faced with a wrath of emotion as well as the need to decide on treatment. The decision on whether to undergo breast conserving survey or mastectomy is difficult and too often determined by physician decision rather than the patient. The factors that influence decision are complicated and proper patient education is important to better guide patients through this challenging decision-making process. Despite data that still supports breast conserving surgery for some patients, a large percentage of these women still choose mastectomy.

2.6.1 Ductal Carcinoma in situ and mastectomy

Ductal carcinoma in situ (DCIS) is becoming more frequently diagnosed due to advancements in diagnostic mammography. Prior to mammography, DCIS was rarely detected. DCIS typically appears as abnormal calcifications but can also appear as a palpable mass. DCIS represents a production of cells with a malignant-like appearance that have not invaded beyond the ducts as shown in Figure 9. Since DCIS is limited to the ductal system, DCIS is considered a non-invasive cancer and considered a precursor for the development of invasive breast cancer. While there is a strong association between DCIS and invasive breast cancer, the progression is still unknown. There is no standardized treatment for DCIS however, mastectomy was the first treatment option with a disease survival rate of 99.1% at 10 years. [51]

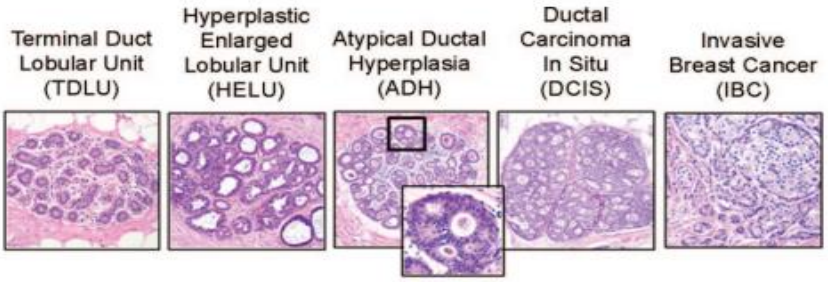


Figure 9 Evolution of Ductal (invasive) Breast Cancer

2.7 Mastectomy and age

There has been progress in the surgical management of breast cancer with evidence supporting breast conservation, however, breast conserving surgery has continued to be underutilized in many areas geographically and demographic populations. [52] A study conducted by Stefanie P. Lazow, M.D. et al, focused on patients under the age of 40 with stage 1 breast cancer. The goal of this study was to identify if demographic factors were associated with choice of treatment. The study also provided a comparison of overall survival between breast conserving surgery and mastectomy. The study identified 306,877 female patients from the period 2004 through 2014. Approximately 11,859 patients were under the age of 40 at the time they were diagnosed with stage 1 breast cancer as shown in Table 2.

Table 2 Demographic factors associated with choice of treatment

	N (%)
Age <40	11 859 (100%)
Female	11 859 (100%)
Mean age (y), (±SD, range)	35.1 (±3.7, 18-39)
Ethnicity	
Non-Hispanic Caucasian	8230 (69.4%)
Hispanic	884 (7.5%)
Black	1289 (10.9%)
Other	1456 (12.3%)
Residence type	
Metro	10 117 (85.3%)
Urban	1039 (8.8%)
Rural	332 (2.8%)
Unknown	371 (3.1%)
Socioeconomic status	
Residing in zip code with highest quartile of annual income (>$63 000)	5005 (42.2%)
Residing in zip code with lower 3 quartiles of annual income (<$63 000)	6854 (57.8%)
Insurance status	
Private insurance	9822 (82.8%)
Government insurance (medicaid or medicare)	1540 (13.0%)
Not insured	497 (4.2%)

Many patients included in this study underwent complete mastectomy (n=6785, 57.2%) rather than breast conserving surgery. Of those who underwent complete mastectomy, 39% underwent unilateral and 61% underwent bilateral. The study reported mastectomy rates were significantly higher in 2014 in comparison to 2004 (2004 bilateral mastectomy rate: 31.7% in 2004 compared to 73% in 2014). A review of insurance revealed patients with privately held insurance had higher rates of mastectomy compared to government

insurance and those that held no insurance. Additionally, patients of high socioeconomic status had higher rates of mastectomy than those of lower economic status. Non-Hispanic White patients were more likely to elect bilateral mastectomy than unilateral mastectomy.[53]

2.8 Mastectomy and breast reconstruction

In 2014, there were over 102,000 women who underwent breast reconstruction. Breast reconstruction post-mastectomy offers psychological as well as cosmetic benefits when compared to mastectomy alone. Many women who elect reconstruction following mastectomy report improved sexuality as well as overall body image.

In 2008, about 30% of women who elected mastectomy chose to have breast reconstruction. In 1998, the Women's Health and Cancer Rights Act, mandated insurance coverage for breast reconstruction for both group and individual insurance plans. After the passing of this act, reconstruction rates increased from 20.8% in 1998 to 37.8% in 2008. However, despite the passing of health policies and improvements in reconstruction techniques, there are still disparities in breast reconstruction with White women having a higher rate of reconstruction than minority women. This disparity has been attributed to many factors: less knowledge about reconstruction, limited exposure to surgeons to become educated about the procedure and differences in personal beliefs. Additionally, health insurance coverage enables access to medical care. Women with private insurance are more likely to undergo reconstruction than those with Medicare, Medicaid or no insurance.[54]

2.8.1 Mastectomy and type of reconstruction

There are many different types and techniques of breast reconstruction post mastectomy. The two main breast reconstruction techniques are:

- Implant reconstruction: involves placement of expanders during a mastectomy. The silicone envelope like pouches are slowly filled with saline over the course of weeks to months. The implant slowly expands allowing the skin to stretch enough to allow for the permanent implant.
- Autologous or flap reconstruction involves using tissue from another part of your body to reconstruct the breast.
- Nipple-sparing: leaving the nipple and areola complex intact in addition to the breast skin

2.9 Reconstruction and race/ethnicity

Mastectomy is an elective procedure for managing risk or the presence of breast cancer. Women who elect mastectomy can have emotional consequences. Breast reconstruction post mastectomy can have a positive impact by improving body image thereby improving overall qualify of lie. Studies have found that the cancer recurrence rate as well as a patient's mortality are not adversely affected by reconstruction. Reconstruction is now routinely considered as part two of the mastectomy surgery. There are several options available for breast reconstruction. There are also sociodemographic and clinical factors that can influence a patient's acceptance of this procedure. A study conducted at University of California Irvine collected satisfaction surveys from women who elected immediate breast reconstruction from 2012 through 2014. With respect to race, 80% of

the patients were White, 11% were Hispanic, 7.8% Asian and 1% were African American. An analysis of insurance revealed the highest percentage 72.2% had private insurance, 13% had Medicare, 12% had Medicaid, there were no uninsured patients. Patient medical histories revealed 52.2% had at least 1 comorbidity, 34.4% had 2-3 comorbidities and 13.3% had greater than 3 comorbidities. With respect to timing of reconstruction, 68.9% had immediate reconstruction (day of mastectomy), while 31.1% had delayed reconstruction. An evaluation of type of reconstruction revealed, 47.7% had tissue expanders inserted, while 52.3% had autologous reconstruction. With respect to type of mastectomy, 52.5% underwent bilateral mastectomy, while 47.7% had unilateral mastectomy. [55]

2.10 Reconstruction and comorbidities

Since 2000, studies using the National Cancer Database and the Surveillance, Epidemiology and End Results data (SEER) have shown there has been an upward trend in mastectomy rates. The data does not clearly outline why. In 2014, there were an estimate 102,000 women who elected mastectomy followed by breast reconstruction. This was an increase of 30% since 2000. [56] Despite the Women's Health and Cancer Rights Act of 1998 which eliminated financial constraints associated with reconstruction, breast reconstruction remains underutilized. A review of the literature suggests that the lack of reconstruction is associated with low economic status, age of patient, race/ethnicity and treatment received in a non-cancer hospital. Additionally, comorbidities such as obesity, which affects approximately 36% of women, is a factor which may preclude reconstruction. [57]

In a study was conducted by Jinhai Huo, et al., utilizing data from the MarketScan Health Risk Assessment (HRA) database which collects health information from approximately 45 self-insured employers who contract with Truven Health to manage overall cost of their health plans. The MarketScan database identified 2558 patients treated with mastectomy during the period 2009 through 2012. Of the 2558 patients, 71.3% had breast reconstruction post mastectomy. The demographics of these patients: (mean age 52), received bilateral mastectomy, no chemotherapy, radiation treatment, cardiovascular disease, diabetes or hypertension. Obesity was a factor in patients who elected reconstruction. The overall reconstruction rate of non-obese patients was significantly higher 76.2% than those in obese class I and class II and III 63.3% and 60.2% respectively. The complication rate post-reconstruction for obese class I, body mass index (BMI) 30-34 kg/m^2, and class II and III (BMI $\geq$ 35 kg/m^2 was 42.0% and 49.6% respectively compared to non-obese patients 32.2%. [58]

2.11 Reconstruction and the risk of complications

Mastectomy is an elective procedure requiring minimal hospital stay. An increasing number of women are electing mastectomy. Reconstruction post mastectomy can be performed using various techniques. Patients who elect autologous breast reconstruction such as latissimus dorsi myocutaneous flap, TRAM, DIEP, or GAP flap are at greater risk for wound complications compared to women who elect tissue expanders followed by the placement of permanent implants. Patients who undergo autologous reconstruction also are at risk for seroma, fat necrosis as well as flap contracture. A meta-analysis conducted in 2013 by Lee et al., examined factors leading to postoperative complications related to

TRAM, DIEP and SIEA flap reconstruction. The study concluded that obesity increases the risk of flap complications. [59]

In contrast to autologous reconstruction, patient who receive breast implants are at risk for capsular contracture (hardening of the implant), skin necrosis and issues with wound and tissue healing. These complications can result in the need for surgical revisions and/or implant removal.

2.12 Mastectomy and insurance coverage

There are over three million women in the United States with a known history of breast cancer, and approximately 12% of women who are at risk for the development of breast cancer. [60] The Women's Health and Cancer Rights Act of 1998 eliminated the financial barrier associated with breast reconstruction. Despite the elimination of the economic hurdle, studies still report disparities across all demographic groups. Patient education events began in 2012 to help bring awareness regarding breast reconstruction. In 2015, The Breast Cancer Patient Education Act was passed to bring education to women in minority and lower socioeconomic groups regarding breast reconstruction options. A literature review related to insurance and insurance status highlighted the role of insurance and how insurance status plays an integral role in patient's access to breast reconstruction. A study conducted by Parisa Kamali, M.D., published in 2018 in the Plastic Reconstruction Surgery Global Open compared the trends of immediate breast reconstruction between women insured with Medicare with those with privately held insurance before and after the WHCRA. Figure 10 below shows the upward trend between the two groups. Women 64 years of age with private insurance and 66 years of age with Medicare were included in this study. The results of this study showed an

increase in rates of immediate breast reconstruction beginning on or about 1998, regardless of insurance type.[61]

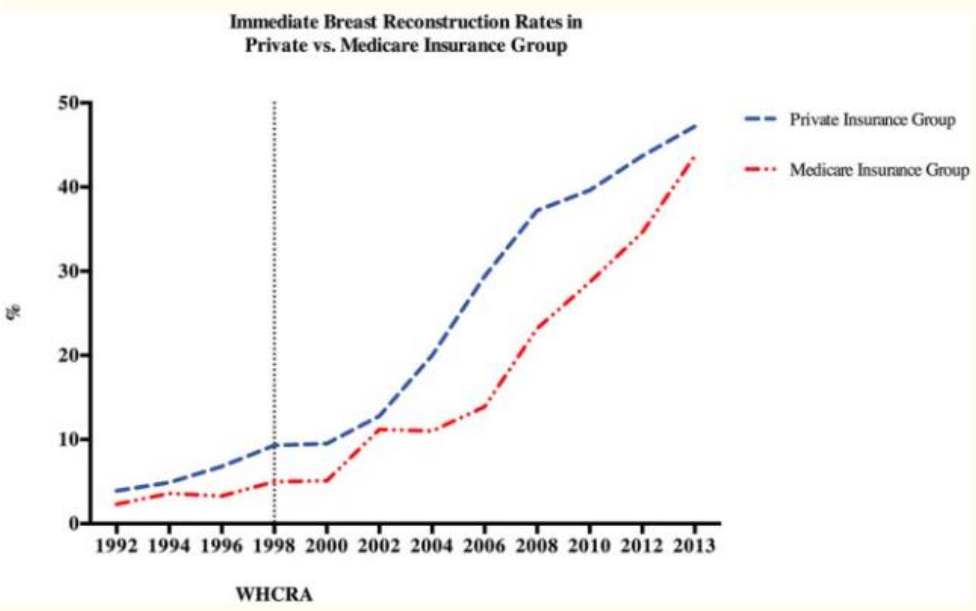


Figure 10 differences in privately insured patients with invasive breast cancer compare with Medicare

2.13 Medicare benefits and mastectomy

The Centers for Medicare and Medicaid Services section (140.2): Breast reconstruction following mastectomy outlined that reconstruction of the affected and the unaffected breast following a medically necessary mastectomy is considered non-cosmetic and covered under Medicare for any medical reason. Medicare Part A will cover inpatient hospital coverage. The coverage of Part A includes mastectomy surgery as well reconstruction. Part A benefits will cover surgical implants after mastectomy if the surgery occurs in an inpatient setting. For patients who are at an increased risk for breast cancer and who elect prophylactic mastectomy due to family history or genetic

mutations, insurance coverage will vary based on the state you live in. There are certain states that require coverage by law. The limitation on length of stay was not outlined by the Centers for Medicare and Medicaid manual.

2.14 Literature Search Strategy

A search of the Rutgers University Library which provided access to various library databases. The search is depicted in Table 3.

Table 3. Database Search

Database	Search Terms
PubMed	mastectomy, prophylactic mastectomy, economic drivers, breast cancer
Google Scholar	history of mastectomy, breast cancer,
PubMed Central	mastectomy, propylactic mastectomy, BRCA mutation, LCIS
Journals Ovid	mastectomy,prophylactic mastectecty,
Cochrane Library	contralateral mastectomy, prophlactic mastectomy, prophylactic bilateral mastectomy

The literature review search was limited to the last 10 years. The reason for such a large span of time was to see the advancement in surgical technique as well as the evolving research related to surgical management. The research focused on peer-reviewed, meta and quantitative analysis. Publications that matched the search terms were selected and evaluated for association with cost of care, socioeconomic factors, breast cancer and risk management.

CHAPTER III

MATERIAL AND METHODS

3.1 National inpatient sample dataset

The data from the 2008-2011 National Inpatient Sample (NIS), was utilized in this study. The NIS is part of the Healthcare Cost and Utilization Project (HCUP), sponsored by the Agency for Healthcare Research and Quality (AHRQ), formerly the Agency for Healthcare Policy and Research. The NIS is a database of hospital stays in the United States. Researchers and policy makers use the NIS to identify, track and analyze national trends in healthcare utilization access, charges, qualify and outcomes. IBM-SPSS version 22 statistical software used to analyze the data.

3.2 Data and methods

For this study, the cases selected were based on specific ICD 9 codes. The total visits for mastectomy patients totaled 56,676 from the years 2008 through 2011 from 1,040 hospitals in forty-four States. There were 895 males excluded from the dataset leaving the final mastectomy universe totaling 55,781. The data elements utilized from the NIS dataset involved both clinical and non-clinical information. Non-clinical data elements included socio-demographic characteristics, median household income, insurance information, hospital status, length of stay and total charges. Clinical data elements included, comorbidities, number of procedures, number of chronic conditions and mortality. Based on the hypotheses of this study, the length of stay, total charges and mortality were defined as the dependent variables, while patient specific information such as race, age, gender, insurance type and median household income were independent

variables. All results with *p value* less than 0.05 were considered significant. The inferential statistics used in this study were Chi-Square, Pearson correlation, logistic regression and multiple linear regression (dummy method). The dummy method was used as a method to determine the predictors of length of stay and total charges. In regression analysis, a dummy variable is dichotomous or categorical and takes on the value 0 or 1, where 0 refers to the absence and 1 refers to presence. A dummy variable is used to represent subgroups of the sample in the study. Chi-Square test of independence was used to tell us if the observed pattern is statistically different from the pattern expected due to chance. Pearson correlation measures the linear relationship between two variables such as length of stay, total charges and number of chronic conditions. Regression is used to investigate the effect of one or more predictor variables on the outcome variable. In this study regression was used to determine the predictors of length of hospital stay, total charges and mortality.

3.3 Data variables used in this study

The data elements in the NIS Inpatient data are listed in Table 4. The data elements used in the study are found in either in the core, hospital or severity files of the NIS dataset. There were additional dummy dichotomous variables created and defined by ICD-9-CM procedure codes and ICD 9 diagnostic codes.

Table 4. Data variables used in study

Study Variable	NIS Variable	Description	Variable type
AGE	AGE	Age in years	numerical
MORTALITY	DIED	Patient died = 0 Patient did not die = 1	categorical
GENDER	FEMALE	FEMALE = 1 is female	categorical
TOTAL_CHARGE	TOTCHG	total charges	numerical
RACE	RACE	1=white, 2=black 3-Hispanic, 4-Asian-Pacific, 5=Native Am, 6= other	categorical
INSURANCE TYPE	PAY1	1=Medicare, 2=Medicaid, 3=private, 4=self-pay, 6=other	categorical
NUMBER OF PROCEDURES	NPR	number of procedures performed while patient was hospitalized	numerical
SOCIO-ECONOMIC STATUS	ZIPINC_QRTL	Median household income for patient's Zip code, 1=0-25th percentile, 2-26th-50th percential, 3=51-75th percentile, 4=76th-100th percentile	categorical
COMORBIDITIES	CM_AIDS, CM_ALCOHOL, CM_ANEMDEF, CM_ARTH, CM_BLDLOSS, CM_CHF, CM_CHRNLUNG, CM_COAG, CMDEPRESS, CM_DM, CM_DMCX, CM_DRUG, CM_HTN_C, CM_HYPOTHY, CM_LIVER, CM_LYMPTH, CM_LYTES, CM_METS, CM_NEURO, CM_OBESE, CM_PARA, CM_PERIVASC, CM_PSYCH, CM_PULMCIRC, CM_RENFAIL, CM_TUMOR, CM_ULCER, CM_VALVE, CM_WGTHLOSS,	AIDS, ALCOHOL, ANEMIA DEFICIENCY, ARTHRITIS, BLOODLOSS, CONGESTIVE HEART FAILURE, COAGULATION, DEPRESSION, DIABETES UNCOMPLICATED, DIABETES WITH CHRONIC COMPLICATIONS, DRUG ABUSE, HYPERTENSION, HYPOTHROIDISM, LIVER DISEASE, LYMPHOMA, FLUID AND ELECTROLYE DISORDERS, METASTATIC CANCER, NEUROLOGICAL DISORDERS, OBESITY, PARALYSIS, PERIPHERAL VASCULAR, PSYCHOSES, PULMONARY CIRULATION DISORDERS, RENAL FAILURE, SOLID TUMOR WITHOUT METASTESES, PEPTIC ULCER DISEASE EXCLUDING BLEEDING, VALVULAR DISEASE, WEIGHT LOSS	categorical
LENGTH OF STAY	LOS	number of days hospitalized	numerical
NUMBER OF CHRONIC CONDITIONS	NCHRONIC	number of chronic conditions	numerical
UNILATERAL MASTECTOMY	unilateral_mastectomy	85.41, 85.43, 85,45, 85.47	categorical
BILATERAL MASTECTOMY	bilaeral_mastectoy	85.40, 85.42, 85.44, 85.46	categorical
PERSONAL HISTORY OF BREAST CANCER	personal_history_BC	V10.3	categorical
FAMILY HISTORY OF BREAST CANCER	family_history_BC	V16.3	categorical
PROPHYLACTIC ORGAN REMOVAL-BREAST	Prophylactic_Breast Removal	V50.41, 233.0	categorical

3.3 Data variables continued

TOTAL RECONSTRUCTION	total_reconstruction	85.7	categorical
BILATERAL BREAST IMPLANT	Bilateral_Breast_Implant	86.54	categorical
UNILATERAL BREAST IMPLANT	Unilateral_Breast_Implant	85.53	categorical
CARCINOMA IN SITU OF BREAST	Carcinoma_insitu_Breast	233.0	categorical
INSERTION OF TISSUE EXPANDER	Insertion_Tissue_Expander	85.95	categorical
MALIGNANT	Malignant	174.0-174.9	categorical

3.4 Study hypotheses and statistical tests

The hypothesis listed in Table 5 will be used to answer the research questions. There are ten hypotheses using descriptive and inferential statistics. All research questions, hypotheses, independent, dependent or outcome variables and statistical method used are listed in this table.

Patient information related to ICD 9-CM mastectomy codes (85.41-85.48) were used to extract the mastectomy universe of 55,781 patients from 2008 through 2011. The analysis of these patients, discussion and results will follow in chapter 5 of this paper.

Table 5. Study hypotheses, research questions, and statistical methods

Research Question	Hypothesis	Independent Variable	Dependent or Outcome variable	Stastical Analysis
Are there statistically significant associations between type of mastectomy and total cost?	Hypothesis 1	bilateral_mastectomy	TOTCHG	Linear regression
Are there statistically significant association between type of comorbidity and total cost?	Hypothesis 2	anemia, hypothyroidism, chronic pulmonary disease, depression, diabetes (uncomplicated), hypertension, metastatic cancer, obesity, fluid and electrolyte disorders. weightloss	TOTCHG	Linear Regression
Are there statistically significant associations between prophylactic bilateral mastectomy (PBM) and race, age or economic status?	Hypothesis 3	RACE, AGE, ZIPINC	PBM	logisic regression
Are there statistically significant associations between type of mastectomy and disposition of patient?	Hypothesis 4	unilateral_mastectomy,bilateral_mastectomy	DISPFORM	chi square
Are there statistically significant associations between total cost of mastectomy patients and race, age, or economic status?	Hypothesis 5	RACE, AGE, ZIPINC	TOTCHG	Linear regression
Are there statistically significant associations between length of stay of mastectomy patients and race, age, or economic status?	Hypothesis 6	RACE, AGE, ZIPINC	LOS	Linear regression
Are there statistically significant associations between total cost of mastectomy patients and the various regions of the United States?	Hypothesis 7	HOSP_REGION	TOTCHG	Linear regression
Are there statistically significant associations between total cost of mastectomy patients across the different types of hospital locations?	Hypothesis 8	HOSP_LOCATION	TOTCHG	Linear regression
Are there statistically significant differences in length of stay of mastectomy patients and the different types of payers; Medicare, Medicaid, private, and self-pay?	Hypothesis 9	PAY1	LOS	One-way ANOVA
Are there statistically significant associations between type of comorbididty and mortality?	Hypothesis 10	CM-HTN_C, CM_METS, CM_WGHTLOSS, CM_DM, COAG, CM_ALCOHOL, CM_CHF, CM_CHRNLUMG, CM_DEPRESS, CM_LYTES, CM_ULCER, CM_PERIVASC, CM_OBESE, CM_DMCX, CM_ANEMDEF	DIED	Multinomial logistic regression

Patient information related to mastectomy was extracted from the NIS dataset after reviewing 55,781 hospital entries between the years 2008 and 2011. The preliminary results and analysis will follow in the next chapter.

CHAPTER IV

RESULTS AND ANALYSIS

4.1 Introduction

This chapter will describe the detailed results of the descriptive and inferential statistics. SPSS version 22 was used for the analysis of the NIS dataset for years 2008 through 2011. The mastectomy universe consisted of 56,676 male and female inpatients. For purposes of this study, male patients were excluded, leaving 55,781 total female patients in the resulting dataset. The International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM) procedure used for the mastectomy universe are as follows: 85.41, 85.42, 85.43, 85.44, 85.45, 85.46, 85.47 and 85.48. For all women who underwent mastectomies, we further differentiated between women who underwent a mastectomy for therapeutic reasons and women who underwent mastectomy for risk reduction (prophylactic mastectomy). A woman with unilateral breast cancer could have both a therapeutic mastectomy on the affected breast and a prophylactic mastectomy on the contralateral or unaffected breast. The ICD 9-CM diagnostic code for prophylactic mastectomy is V50.41 - prophylactic organ removal, breast. In reviewing other studies, it was noted that this code may be underutilized, therefore it was necessary to expand the definition. For purposes of this study, a woman was considered to have undergone a mastectomy prophylactically if she had any of the following: 1. Prophylactic bilateral mastectomy diagnostic code (V50.41) , or 2. bilateral mastectomy with a diagnosis of lobular carcinoma in situ (233.0) or 3. Bilateral or unilateral mastectomy without a personal history of breast cancer (V10.3). Dummy dichotomous variables were also created to consolidate unilateral and bilateral mastectomy codes, family history of breast

cancer (V16.3), personal history of breast cancer (V10.3), and breast reconstruction: total reconstruction of breast (85.7, 85.72. 85.74. 85.75, 85.76, 85.79, 85.31, 85.32, 85.33, 85.35, 85.50, 85.51, 85.53, 85.54, 85.6, 85.59, 85.93., 85.94, 85.95, 85.96, 85.8, 85.84, 85.85), insertion of tissue expanders (85.95), unilateral breast implant (85.53) and bilateral breast implant (86.54).

4.2 Demographic characteristics and health information

4.2.1 Age

The mean age range of the study population was 59.23 as shown in Figure 11.

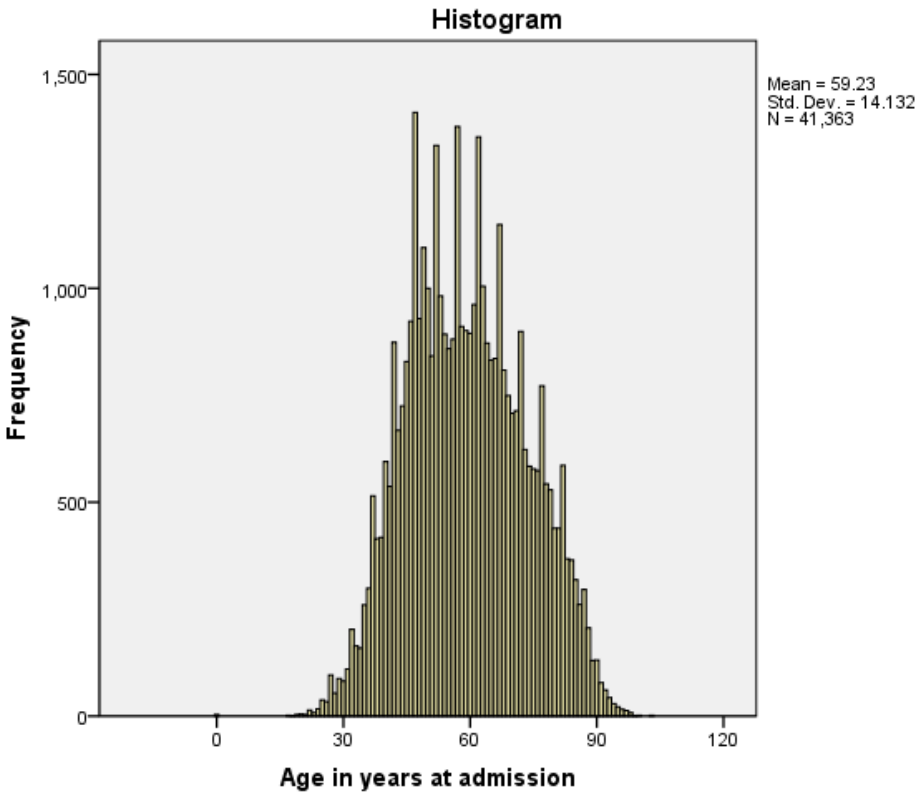


Figure 11 Age in years at admission

The inpatients were categorized into age groups, where the highest number of cases of unilateral mastectomy occurred in the 61-70 age range. The highest number of bilateral mastectomy cases occurred in the 41-50 age range while the lowest number of bilateral

and unilateral cases were shown in women less than 30 years age. The results in Table 6 and Figure 12, show that women greater than 80 years of age continued to have unilateral mastectomy however, bilateral mastectomies were less likely to occur.

Table 6. Mastectomy cases by age group

Age Group	Frequency	Percent
Less than or = 30	471	0.8
31-40	3995	7.2
41-50	11691	21
51-60	13202	23.7
61-70	12554	22.5
71-80	8596	15.4
Greater than 80	5139	9.2

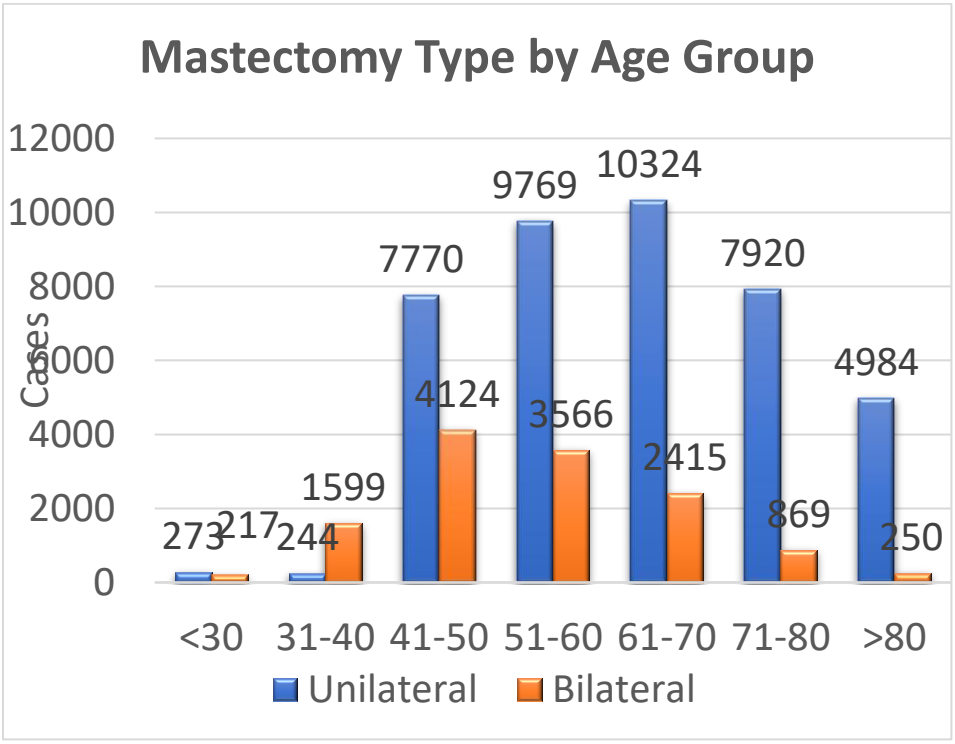


Figure 12 Mastectomy type by age group

4.2.2 Race

The White race had the highest percentage of mastectomy (64.8%) followed by Blacks with (10.2%) as shown in Table 7 and Figure 13. There were 7053 patients that did not declare a race.

Table 7. Frequency of mastectomy by race.

Race		Frequency	Percent
	White	36164	64.8
	Black	5711	10.2
	Hispanic	3669	6.6
	Asian	1664	3.0
	Native American	232	.4
	Other race	1288	2.3
	Total	48728	87.4
Missing	System	7053	12.6
Total		55781	100.0

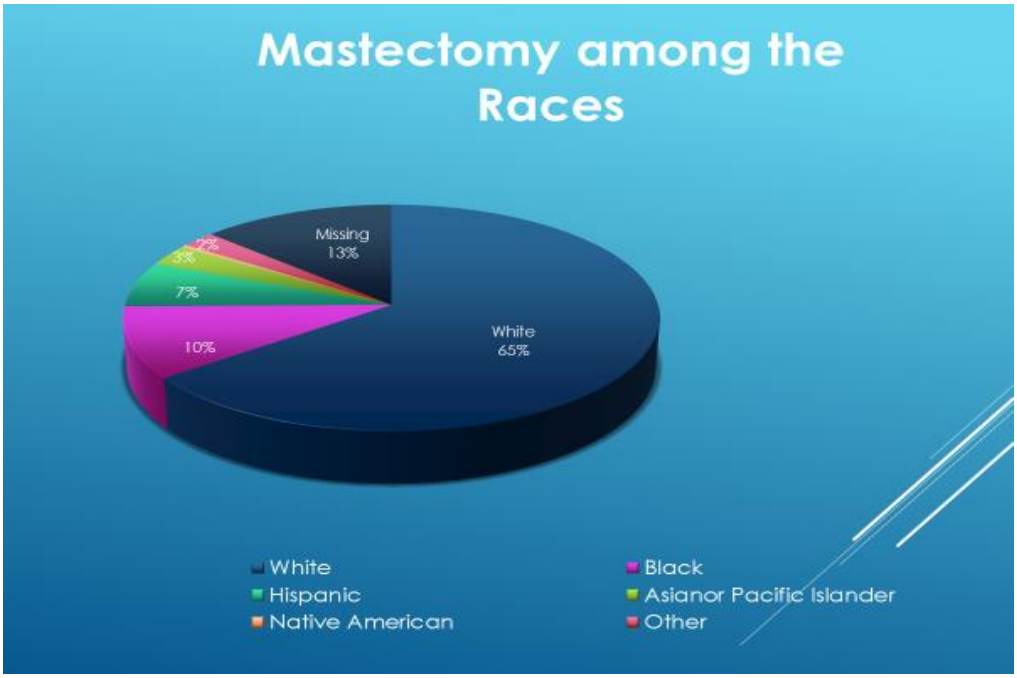


Figure 13 Mastectomy among the races

When we normalized ratios with total number of discharges from 2008 through 2011, we found that White women and Asian women consistently had the highest percentage of discharges each year as shown in Figure 14. The discharge data revealed in this study is supported by recent findings that breast cancer rates have been increasing among Asian-American women over the last 15 years. While most of the racial groups have seen a decline in breast cancer rates, Asian Americans have seen an increase. A study conducted in California from 1988 through 2013, found 548,259 new cases of breast cancer diagnosed in women living there. The study revealed 383,478 cases in non-Hispanic Caucasians and 45,721 in Asian American women. As an individual group, Asian American women experienced a high increase in breast cancer compared to non-Hispanic Caucasian women.[62] Table 8 below shows mastectomy discharges for White and Asian populations from the period 2008 through 2011. Asians also had the highest number of discharges in the west.

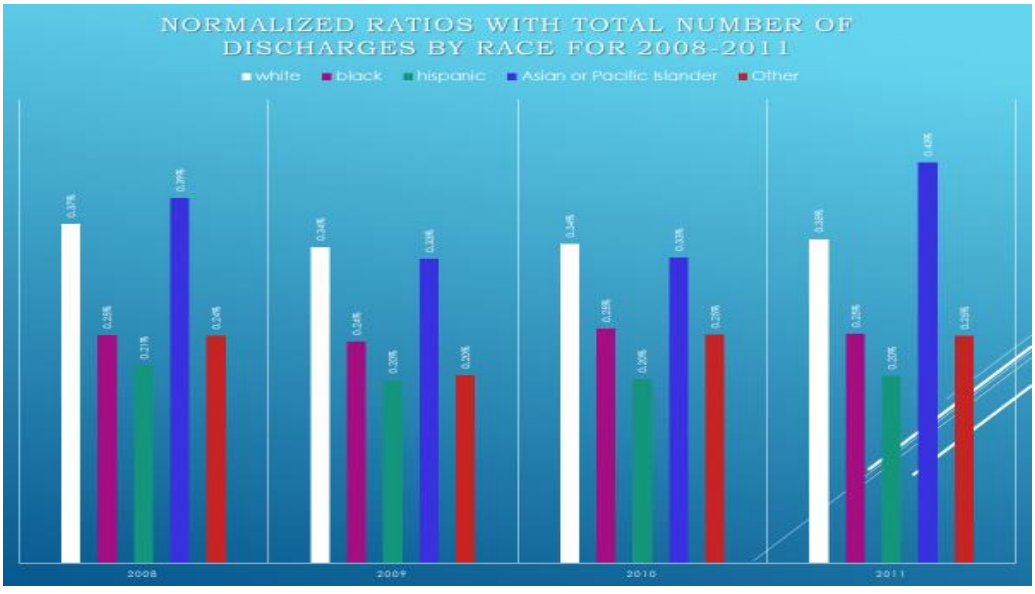
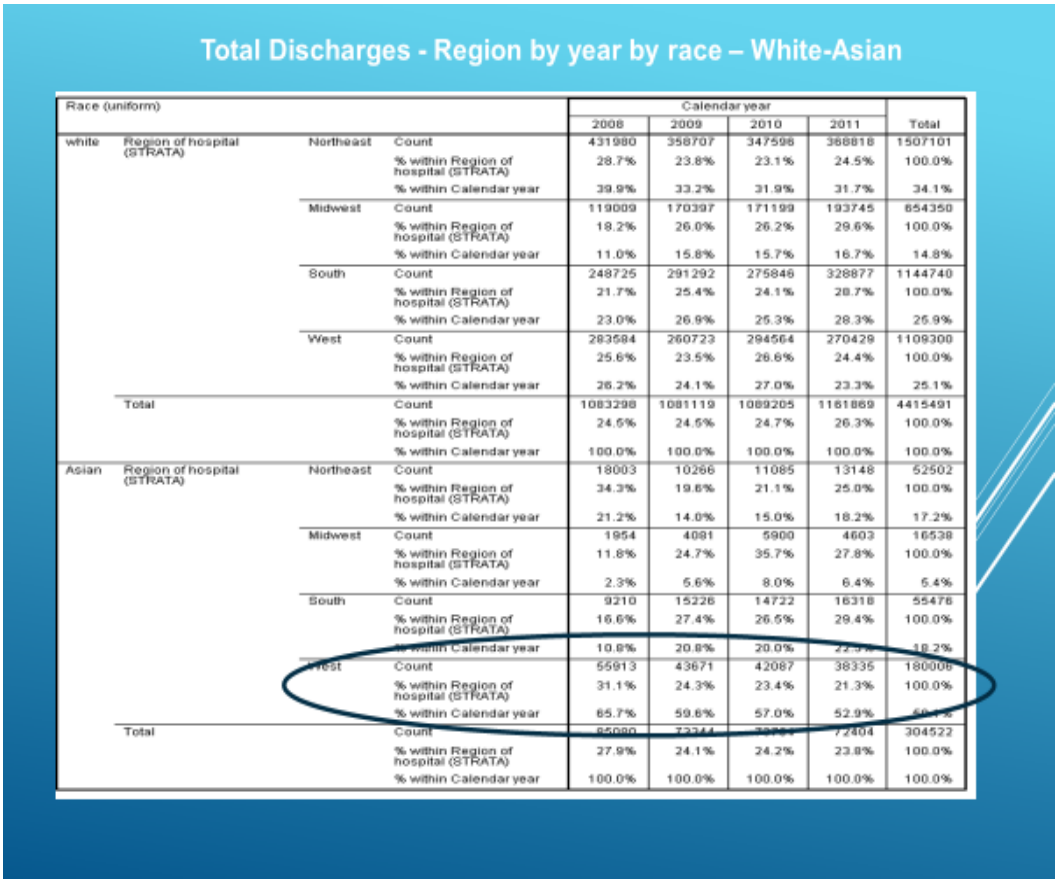


Figure 14 Normalized ratios with total number of discharges by race for 2008-2011

Table 8 Total discharges (White -Asian) by region – 2008-2011



Race (uniform)				Calendar year				
				2008	2009	2010	2011	Total
white	Region of hospital (STRATA)	Northeast	Count	431980	358707	347598	368818	1507101
			% within Region of hospital (STRATA)	28.7%	23.8%	23.1%	24.5%	100.0%
			% within Calendar year	39.9%	33.2%	31.9%	31.7%	34.1%
		Midwest	Count	119009	170397	171199	193745	654350
			% within Region of hospital (STRATA)	18.2%	26.0%	26.2%	29.6%	100.0%
			% within Calendar year	11.0%	15.8%	15.7%	16.7%	14.8%
		South	Count	248725	291292	275846	328877	1144740
			% within Region of hospital (STRATA)	21.7%	25.4%	24.1%	28.7%	100.0%
			% within Calendar year	23.0%	26.9%	25.3%	28.3%	25.9%
		West	Count	283584	260723	294564	270429	1109300
			% within Region of hospital (STRATA)	25.6%	23.5%	26.6%	24.4%	100.0%
			% within Calendar year	26.2%	24.1%	27.0%	23.3%	25.1%
	Total		Count	1083298	1081119	1089205	1161869	4415491
			% within Region of hospital (STRATA)	24.5%	24.5%	24.7%	26.3%	100.0%
			% within Calendar year	100.0%	100.0%	100.0%	100.0%	100.0%
Asian	Region of hospital (STRATA)	Northeast	Count	18003	10266	11085	13148	52502
			% within Region of hospital (STRATA)	34.3%	19.6%	21.1%	25.0%	100.0%
			% within Calendar year	21.2%	14.0%	15.0%	18.2%	17.2%
		Midwest	Count	1954	4081	5900	4603	16538
			% within Region of hospital (STRATA)	11.8%	24.7%	35.7%	27.8%	100.0%
			% within Calendar year	2.3%	5.6%	8.0%	6.4%	5.4%
		South	Count	9210	15226	14722	16318	55476
			% within Region of hospital (STRATA)	16.6%	27.4%	26.5%	29.4%	100.0%
			% within Calendar year	10.8%	20.8%	20.0%	22.5%	18.2%
		West	Count	55913	43671	42087	38335	180006
			% within Region of hospital (STRATA)	31.1%	24.3%	23.4%	21.3%	100.0%
			% within Calendar year	65.7%	59.6%	57.0%	52.9%	59.1%
	Total		Count	85080	73244	73894	72404	304522
			% within Region of hospital (STRATA)	27.9%	24.1%	24.2%	23.8%	100.0%
			% within Calendar year	100.0%	100.0%	100.0%	100.0%	100.0%

4.2.3 Health Insurance

Illustrated in Table 9 and Figure 15, private insurance was the main form of health insurance with the highest percentage (50.7%) followed by Medicare at (36.7%)

Table 9 Mastectomy patients and health insurance

	Health Insurance	Frequency	Percent
	Medicare	20446	36.7
	Medicaid	4860	8.7
	Private Insurance	28290	50.7
	Self-pay	711	1.3
	No-Pay	177	.3
	Other	1222	2.2
	Total	55706	99.9
Missing	System	75	.1
Total		55781	100.0

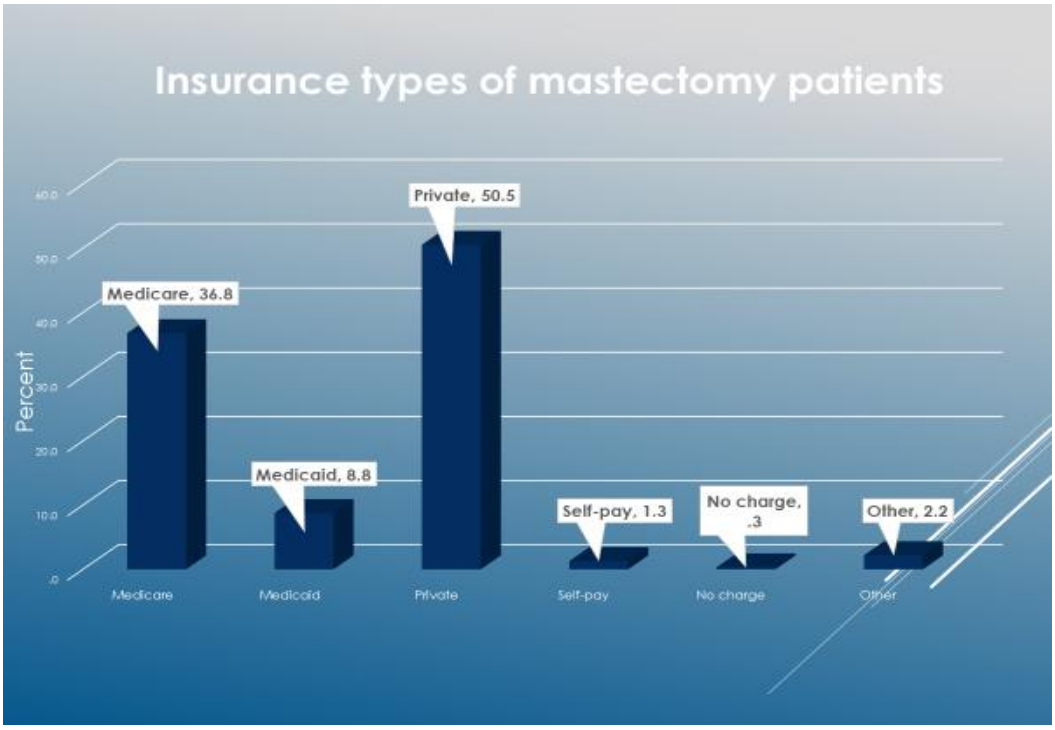


Figure 15. Insurance types of mastectomy patients

4.2.4 Patient comorbidities

The highest incidence of comorbidities for mastectomy patients was observed for hypertension (complicated-non-complicated) with (41.7%), followed by diabetes uncomplicated with (13.4%), chronic pulmonary disease with (11.5%) and hypothyroidism at (11.2%). Comorbidities with the lowest incidence were acquired immune deficiency syndrome at (0.0%) and peptic ulcer disease excluding bleeding at (0.0%) as shown in Table 10.

Table 10. Frequency of Comorbidities

Comorbidity	Frequency	Percent
Acquired Immune Deficiency Syndrome	14	0.0
Alcohol Abuse	229	0.4
Deficiency Anemias	2929	5.3
Rheumatoid Arthritis - Collagen Vascular Disease	941	1.7
Chronic Blood Loss Anemia	205	0.4
Congestive Heart Failure	1,215	2.2
Chronic Pulmonary Disease	6392	11.5
Coagulopathy	358	0.6
Depression	4725	8.5
Diabetes Uncomplicated	7491	13.4
Diabetes with Chronic Complications	576	1.0
Drug Abuse	160	0.3
Hypertension (complicated and uncomplicated	23246	41.7
Hypothyroidism	6272	11.2
Liver Disease	343	0.6
Lymphoma	139	0.2
Fluid and Electrolyte Disorders	1398	2.5
Metastatic Cancer	5732	10.3
Neurological Disorders	1569	2.8
Obesity	4522	8.1
Paralysis	311	0.6
Peripheral Vascular Disorders	676	1.2
Psychoses	923	1.7
Pulmonary Circulation Disorders	329	0.6
Renal Failure	1095	2.0
Solid Tumor without Metastasis	946	1.7
Peptic Ulcer Disease Excluding Bleeding	8	0.0
Valvular Disease	1589	2.8
Weight Loss	246	0.4

4.2.5 Mortality

The incidence of mortality among mastectomy patients was approximately (.1%) of the population as shown in Table 11. While mastectomy is an elective procedure with known complications, a high rate of mortality would not be expected.

Table 11. Mortality of mastectomy patients

		Frequency	Percent
	Did not die	55612	99.7
	Died	42	.1
	Total	55654	99.8
Missing	System	127	.2
Total		55781	100.0

When we normalized ratios for mortality by race for years 2008 through 2011 the analysis revealed Blacks had the highest mortality for 2008 (0.025%), 2009 (0.019 %) and 2011 (0.016%). In 2010, the White race had the highest incidence of mortality (0.006%) as shown in Figures 16, 17, 18 and 19.

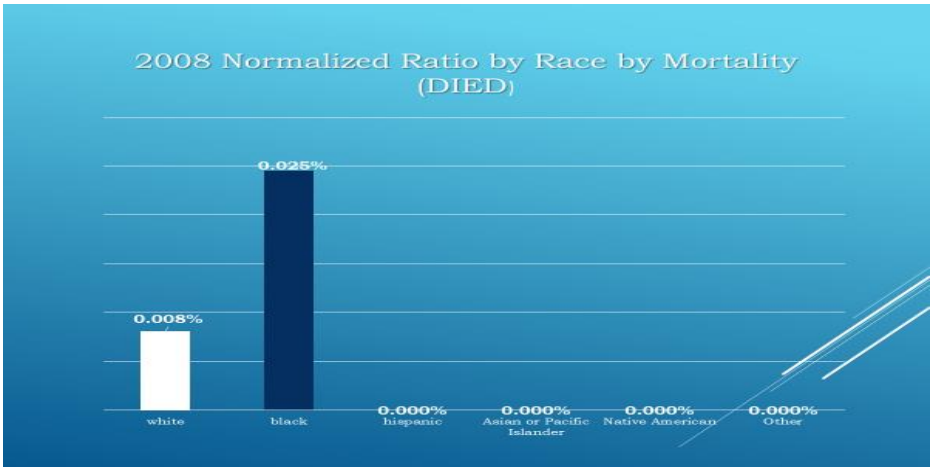


Figure 16 2008 Normalized ratio by race by mortality (DIED)

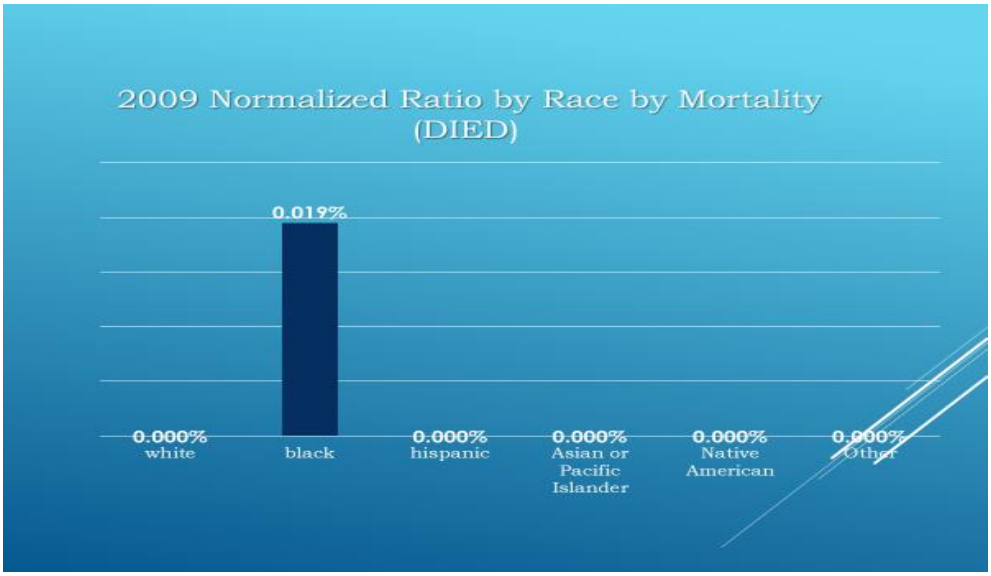


Figure 17 2009 Normalized ratio by race by mortality (DIED)

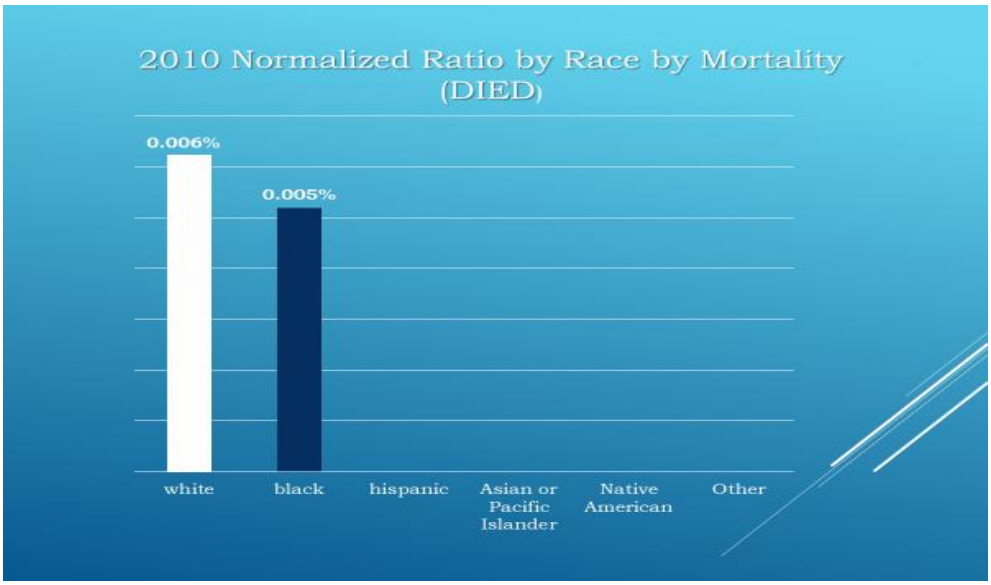


Figure 18 2010 Normalized ratio by race by mortality (DIED)

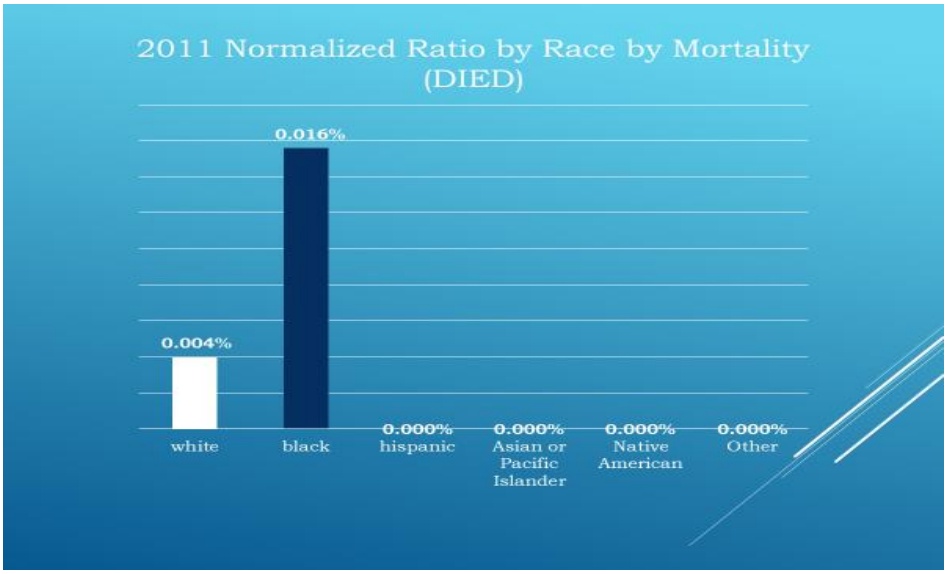


Figure 19 2011 Normalized ratio by race by mortality (DIED)

4.2.6 Comorbidities and mortality among African American population

There were 43 deaths among the mastectomy population, 23 White, 10 Black and the remaining 10 did not declare race. An examination of the comorbidities within the Black population revealed the highest comorbidity count was hypertension and fluid an electrolyte disorders followed by metastatic cancer. Of the 10 patients each the majority had at least two or more comorbidities with the highest comorbidity count being 6 as shown in Table 12.

Table 12 Mortality and total comorbidities

Patient ID	AHRQ comorbidity measure: Deficiency anemias	AHRQ comorbidity measure: Congestive heart failure	AHRQ comorbidity measure: Metastatic cancer	AHRQ comorbidity measure: Pulmonary circulation disorders	AHRQ comorbidity measure: Diabetes, uncomplicated	AHRQ comorbidity measure: Diabetes with chronic complications	AHRQ comorbidity measure: Hypertension (combine uncomplicated and complicated)	AHRQ comorbidity measure: Fluid and electrolyte disorders	AHRQ comorbidity measure: Liver disease	AHRQ comorbidity measure: Peripheral vascular disorders	AHRQ comorbidity measure: Obesity	AHRQ comorbidity measure: Coagulopathy
1651	0	0	0	0	1	0	1	0	1	1	0	0
6589	0	0	0	0	0	0	0	0	0	0	0	0
9420	0	0	1	0	0	0	1	1	0	0	0	0
12494	0	0	0	0	1	0	1	1	0	0	0	1
12666	0	0	0	0	0	0	1	0	0	0	0	0
15086	0	0	1	0	0	0	0	0	0	0	0	0
36487	0	1	1	0	1	0	1	1	0	0	0	1
37649	0	1	0	1	0	1	1	1	0	0	0	0
41854	0	0	1	0	0	0	0	1	0	0	0	1
55753	1	1	1	1	0	0	0	1	0	0	0	0
Died	10	10	10	10	10	10	10	10	10	10	10	10
Total Comorbidites	1	3	5	2	3	1	6	6	1	1	0	3

4.2.7 Mastectomy length of stay and total charges

The mean length of stay for mastectomy patients was 2.19 days (± 2.496) days. The mean total cost was $35303.76 (±$31081) as shown in Table 13.

Table 13. Length of hospital stay and total charge of mastectomy patients

Paramter	Mean	Median	Std. Dev	Skewness	Kurtosis
Length of stay (days)	2.19	2.00	2.496	13.391	408.942
Total Cost ($)	35303.76	26806.00	31081.6	6.622	163.345

4.2.8 Median household income

There are four median income quartiles based on patient zip codes. The median income quartiles are defined as follows: 0-25th percentile ($1-$38,999); 26-50th percentile ($39,000-$47,999); 51st-75th percentile ($48,000-$63,999) and 76th-100th percentile ($64,000 or more). The percentage of median income for mastectomy patients is as follows: 22.2% (Quartile 1), 23.5% (Quartile 2), 24.9% (Quartile 3) and 29.4% (Quartile 4) as shown in Figure 20.

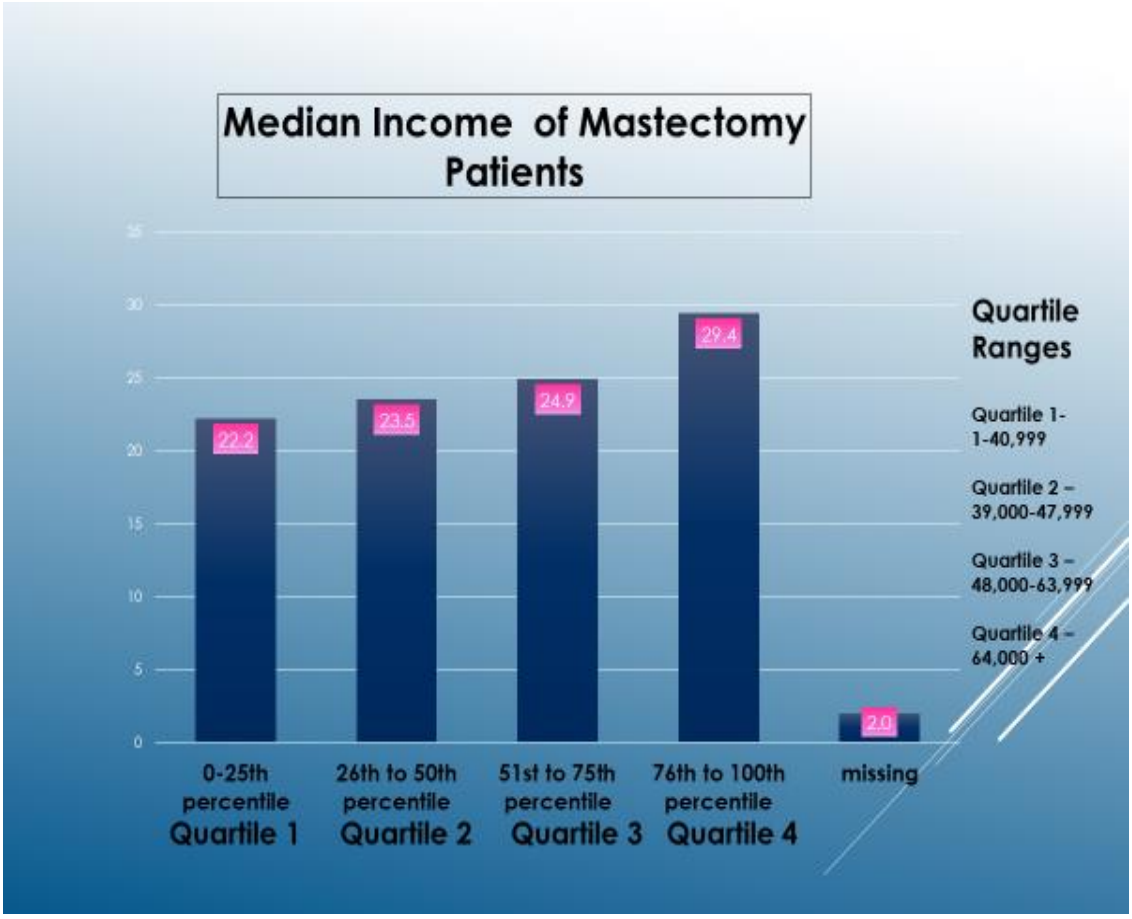


Figure 20 Median household income of mastectomy patients

4.2.9 Frequency of hospital admission by year

This study involved all patients admitted to the hospital in the United States from 2008 through 2011. The admission rate throughout the four years was consistent with only a minor reduction in admissions in 2009 and 2010 at (23.8%) and (23.9%). The year 2008 had the highest number of admissions (26.8%) as shown in Table 14.

Table 14. Hospital admissions of mastectomy patients from 2008-2011

	Frequency	Percent
2008	14931	26.8
2009	13269	23.8
2010	13317	23.9
2011	14264	25.6
Total	55781	100.0

4.2.10 Admission type

The six types of admissions into hospitals are emergency department, urgent, elective, other and trauma. The highest incidence of admissions was elective (78.1%), followed by urgent (6.9%) and emergency department (2.0%), with the lowest incidence being within the other and trauma shown in Table 15.

Table 15 Type of admission

		Frequency	Percent
	Emergency	1126	2.0
	Urgent	3828	6.9
	Elective	43553	78.1
	Other	2	.0
	Trauma	6	.0
	Total	48515	87.0
Missing	System	7266	13.0
Total		55781	100.0

4.2.11 Number of chronic diseases and number of procedures

The mean number of chronic diseases for mastectomy patients is 3.43 (±2.623). The mean number of procedures for mastectomy patients is 2.66 (±1.638) as shown in table 16.

Table 16. Number of chronic diseases and number of procedures of mastectomy patients

Paramdter	Mean	Median	± SD	Skewness	Kurtosis
Number of Chronic Diseases	3.43	3.00	2.623	1.151	1.792
Number of Procdures	2.66	2.00	1.638	1.437	4.738

4.2.12 Prophylactic breast removal

There were 4555 patients who elected prophylactic breast removal (8.2%) as shown in Table 17. Of the 4555 patients, 1176 had a family history of breast cancer and 1016 reported a personal history of breast cancer.

Table 17 Prophylactic breast removal

		Frequency	Percent
	Did not have prophylactic breast removal	51226	91.8
	Did have prophylactic breast removal	4555	8.2
	Total	55781	100.0

The largest population of prophylactic bilateral mastectomy occurred at the age of 47 and 52 with the range being 37-62 years of age as shown in figure 21.

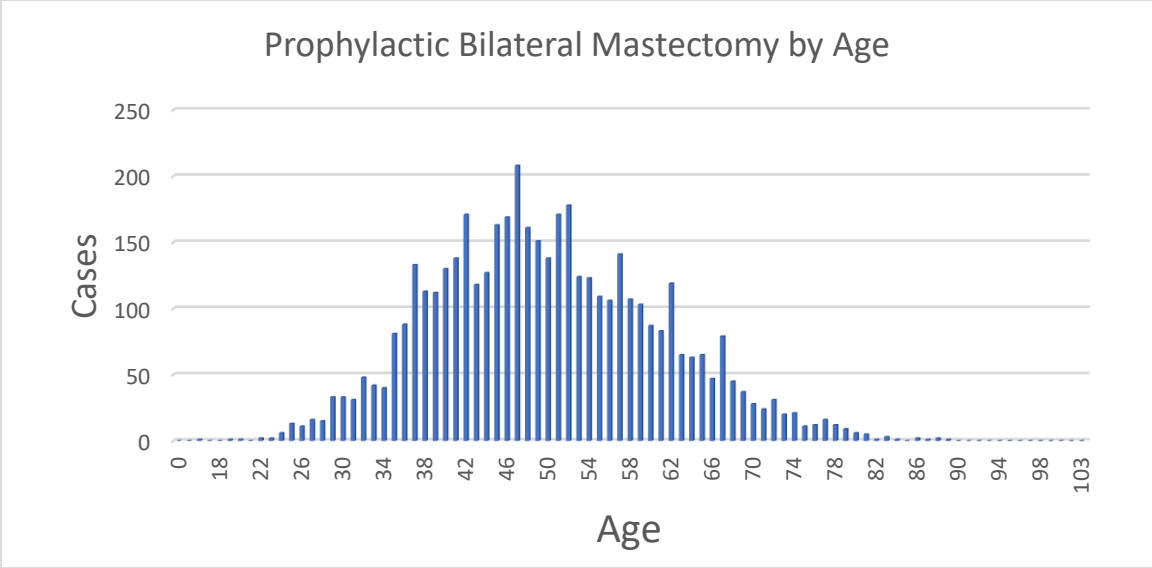


Figure 21 Prophylactic Bilateral mastectomy by age

4.2.13 Malignancy and mastectomy

There were 55,781 patients who elected mastectomy between the years 2008 through 2011. Of the patients who elected mastectomy (81.6%) presented with breast cancer. The highest percentage of cancer was malignant neoplasm unspecified (35.3%) followed by malignant neoplasm other (21.8%) as shown in Table 18.

Table 18 Malignancy and mastectomy

	Frequency	Percent
Malignant neoplasm of the nipple	1048	1.9
Malignant neoplasm of central breast	1932	3.5
Malignant neoplasm of upper inner quadrant	1965	3.5
Maglignat neoplasm of lower inner quadrant	984	1.8
Malignant neoplasm of upper outer quadrant	6469	11.6
Malignant neoplasm of lower outer quadrant	1804	2.9
Malignant neoplasm auxilary tail	185	0.3
Malignant neoplasm other	12142	21.8
Malignant neoplasm unspecified	19710	35.3
Malignant neoplasm Axila	11849	21.2

4.2.14 Mastectomy and history of breast cancer

There were 55, 781 patients who elected mastectomy between the years 2008 through 2011. While (81.6%) of the patients presented with malignancy, only (5.8%) reported a personal history of breast cancer and (7.0%) reported a family history of breast cancer, as shown in Table 19.

Table 19 Mastectomy and breast cancer history

Breast Cancer History	Frequency	Percent
Personal history of breast cancer	3210	5.8
Family history of breast cancer	3928	7.0

4.2.15 Immediate reconstruction and mastectomy

Of the 55781 patients who elected mastectomy, there were 21,532 patient who elected immediate reconstruction as shown in Figure 23. Most mastectomy patients elected to use tissue expanders, (14,544, 26%) followed by TRAM flap (1742, .003%) and latissimus dorsi flap (1168, .002%), shown in Table 20.

The patient characteristics associated with higher rates of immediate reconstruction in younger age women, shown in Figure 22. Although breast reconstruction is offered irrespective of age, it is likely that younger women would elect immediate reconstruction. A Chi-Square test of independence confirmed that there is a relationship between a women's age and her decision to elect immediate reconstruction.

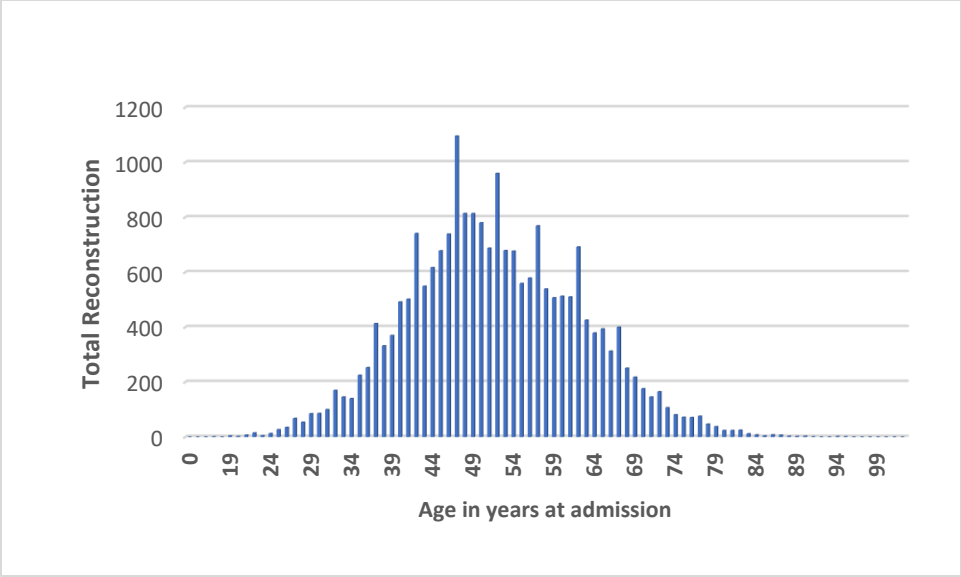


Figure 22 Age and total reconstruction

Race also was a predictor of reconstruction. A cross tabulation revealing that White women had the highest number of reconstruction (41.4%) followed by black (31.5%) and Hispanic (36.4%). While Asians and Whites had the higher number of discharges, the rate of reconstruction for Asians was (34.4%).

When evaluating comorbidity as a predictor of reconstruction, patients with fewer comorbidities were more likely to elect reconstruction.

Table 20 Type of reconstruction

Reconstruction	Frequency	Percentage
Tram Flap	1742	0.03
Latissimus Dorsi Flap	1169	0.02
Gap Flap	35	0.00
Superior Inferior Epigastric	75	0.10
Tissue Expander	14544	26.10

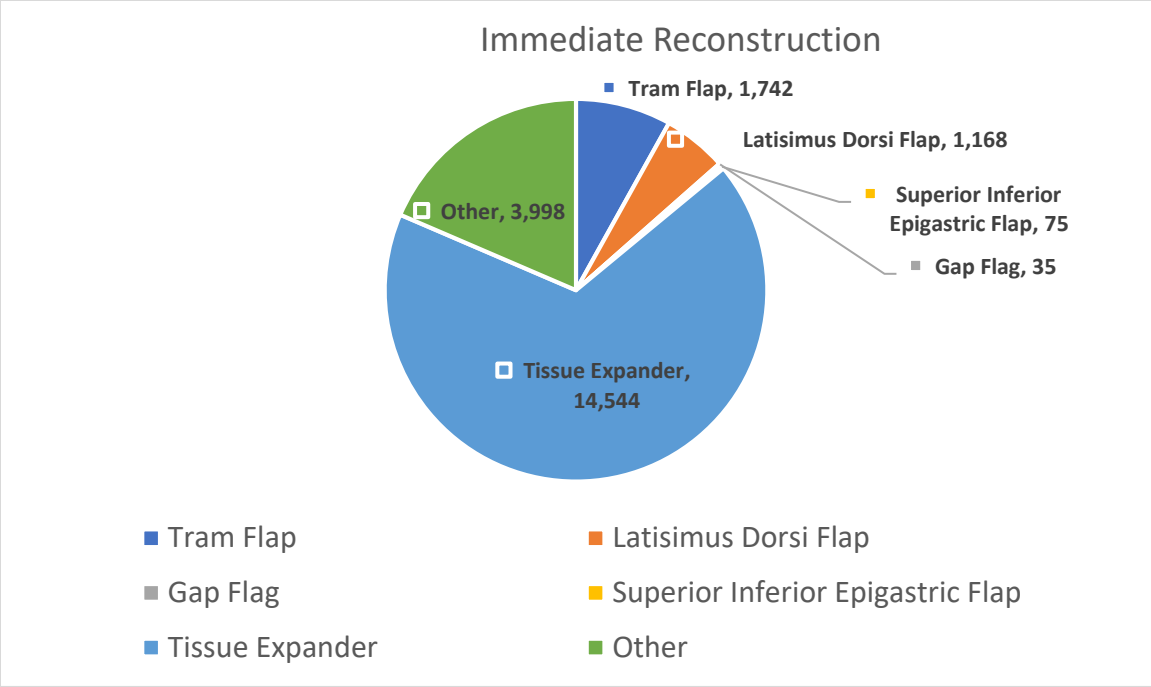


Figure 23 Type of reconstruction

4.2.13 Mastectomy trend 2008 through 2014

A trend analysis using ICD 9 mastectomy codes 85.41 through 85.48 revealed a sharp decline in cases beginning 2011 as shown in Figure 24.

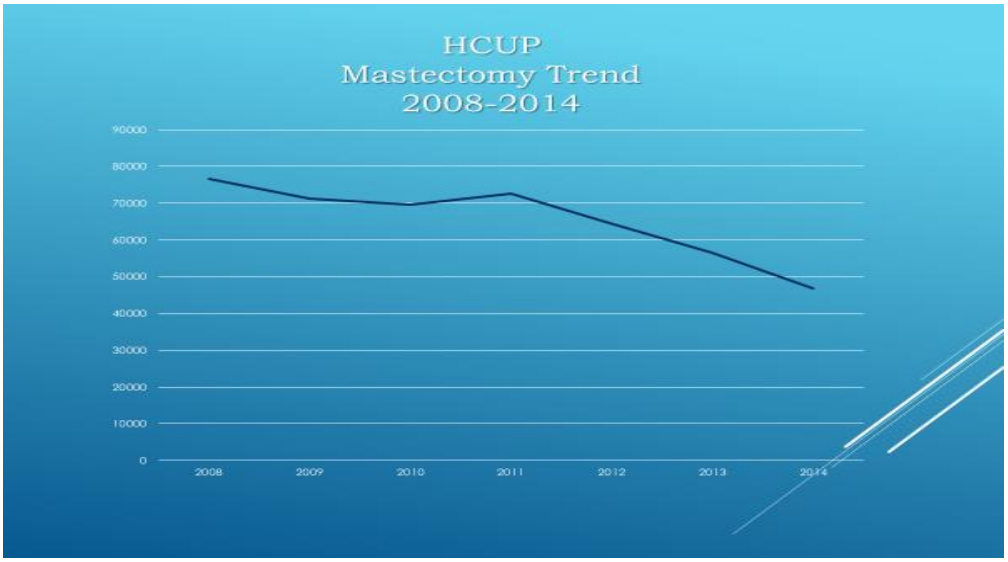


Figure 24 Mastectomy trend 2008-2014

4.3 Predictors and study outcomes

4.3.1 Mastectomy type and total charges (Hypothesis 1)

To predict whether type of mastectomy affected total charges, several assumptions were made to determine final model of outcomes. The assumptions will be displayed first followed by the final model.

Assumption 1, dependent variables should be continuous. Total charges are continuous data. This assumption is accepted.

Assumption 2, two or more independent variables can be either continuous or categorical (ordinal or nominal); Type of mastectomy (unilateral – bilateral), are categorical variables either by their presence or absence using the dummy method. This assumption is accepted.

Assumption 3, independence of observations or independence of residuals. The value of Durbin-Watson for total charges should be between 1 and 3, or near to 2 to be accepted. The Durbin-Watson for total charges is 1.083 for mastectomy patients. This assumption is accepted.

Assumption 4, linear relationship between the dependent and independent variable(s): Significant relationships between dependent and independent variables existed based on significant correlations. This assumption is accepted.

Assumption 5, data must show homoscedasticity: Results indicated that the dots along the Scatterplot remain similar as you move along the line and the same in distance along the linear fit line as shown in Figure 25 below. This assumption is accepted.

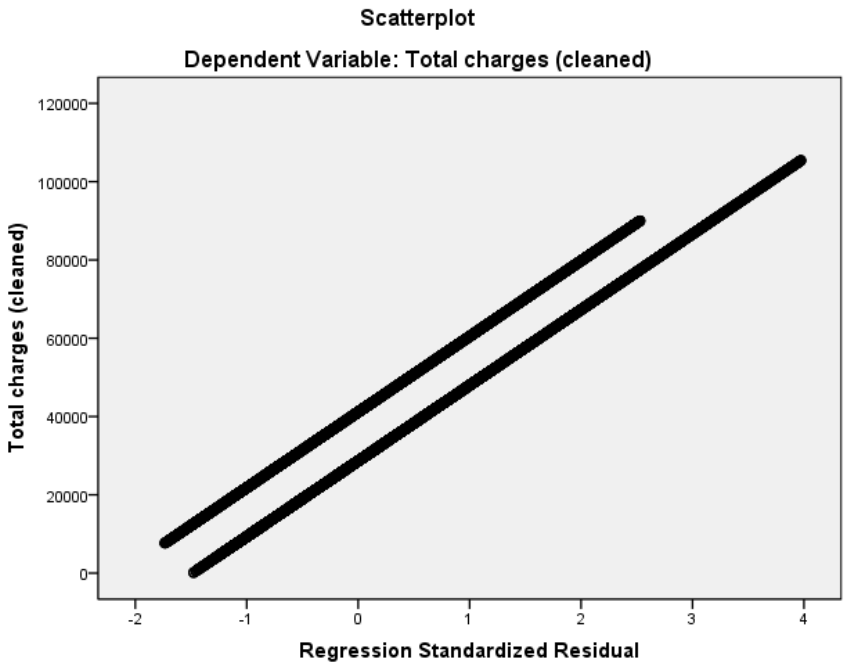


Figure 25. Homoscedasticity of Total Charges (cleaned)

Assumption 6, data must not show multicollinearity: Using collinearity diagnostics, the VIF results must be less than 2 and will be ideal when close to 1. All results of VIF were less than 2, thus this assumption is accepted.

Assumption 7, no significant outliers: The cut point for the outliers while using Cook's distance is (4/n), which is equal to 0.000073. There were 2147 cases considered as outliers. These cases were excluded in the regression model (54427-52280=2147).

Assumption 8, the residuals must be normally distributed: The residuals are normally distributed, as shown in Figure 25 above.

After accepting all assumptions for the total charges, the final models for the predictors of mastectomy patients are shown in Table 20.

The total charges of hospital stay of bilateral mastectomy patients= $28671.80 (constant)+$12487.32

Table 20 Predictors of mastectomy patients

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B		Collinearity Statistics	
		B	Std. Error	Beta			Lower Bound	Upper Bound	Tolerance	VIF
1	(Constant)	28671.797	95.628		299.828	.000	28484.366	28859.228		
	bilateral_Mastectomy	12487.317	204.222	.258	61.146	.000	12087.041	12887.594	1.000	1.000

a. Dependent Variable: Total charges (cleaned)

Linear regression R= .258 (adjust R2=.067), df (1), p<0.001.

4.3.2 Comorbidities and total charges (Hypothesis 2)

Assumption 1, dependent variables should be continuous. Total charges are continuous data. This assumption is accepted.

Assumption 2, two or more independent variables (categorical, numerical or ordinal); Comorbidities are categorical variables. This assumption is accepted.

Assumption 3, independence of observations or independence of residuals. The value of Durbin-Watson for total charges should be between 1 and 3, or near to 2 to be accepted. The Durbin-Watson for total charges is 1.097 for mastectomy patients. This assumption is accepted.

Assumption 4, linear relationship between the dependent and independent variable(s): Significant relationships between dependent and independent variables existed based on significant correlations. This assumption is accepted.

Assumption 5, data must show homoscedasticity: Results indicated that the dots along the scatterplot are homogeneous and the same in distance along the linear fit line as shown in the figure 25 above. This assumption is accepted.

Assumption 6, data must not show multicollinearity: Using collinearity diagnostics, the VIF results must be less than 2 and will be ideal when close to 1. All results of VIF were less than 2, thus this assumption is accepted.

Assumption 7, no significant outliers: The cut point for the outliers while using Cook's distance is (4/n), which is equal to 0.000073. There were 2147 cases considered as outliers. These cases were excluded in the regression model.

Assumption 8, the residuals must be normally distributed: The residuals are normally distributed, as shown in Figure 25 above.

After accepting all assumptions for the total charges, the final model for the predictors of mastectomy patients are shown below in Table 21.

The comorbidity with highest costs for mastectomy patients was found in those with fluid and electrolyte disorders ($11,551.14) followed by weight loss ($6,770.66), anemia ($4,550.00), obesity ($3,650.56) and Depression ($861.44). Those patients where the model indicated a lower total charge were patients with hypertension (-$5,561.14), diabetes uncomplicated ($-2,918.52), chronic pulmonary disease (-957.38) and hypothyroidism (-$246.85). The comorbidity with the highest contribution to total charges is fluid and electrolyte disorder (beta=.085) followed by metastatic cancer and anemia (beta=0.50), obesity (beta=.049) and others.

The total charges= 33077.76 (constant) + 4550.00 (anemia) -246.85 (hypothyroidism) – 957.38 (chronic pulmonary disease) + 861.44 (depression) – 2918.42 (diabetes uncomplicated) -5561.14 (hypertension) + 3318.90 (metastatic cancer) + 3650.56 (obesity) + 11551.14 (fluid and electrolyte disorders) + 6770.66 (weight loss)

Table 21 Predictors of Total Charges

Model	B	Beta	Sig
Constant	33077.76		.000
Anemia	4550.00	0.050	.000
Hypothyroidism	-246.85	-0.004	.366
Chronic Pulmonary Disease	-957.38	-0.015	.000
Depression	861.44	0.012	.005
Diabetes Uncompliated	-2918.52	-0.050	.000
Hypertension	-5561.14	-0.137	.000
Metastatic Cancer	3318.90	0.050	.000
Obesity	3650.56	0.049	.000
Fluid and Electrolyte Disorder	11551.14	0.085	.000
Weight Loss	6770.66	0.020	.000
R=.196, Adjusted R2=.038,	df=10-, p=<0.001		

4.3.3 Relationship between prophylactic bilateral mastectomy and race, age or economic status (Hypothesis 3)

Logistic regression was used to determine the relationship between socioeconomic factors and prophylactic bilateral mastectomy. Women age 51 years and older are significantly less likely to have a prophylactic bilateral mastectomy compared to those less than 31. Black, Hispanic, and Asian are significantly less likely to have a prophylactic bilateral mastectomy compared to whites. Women of higher income level

are more likely to have a prophylactic mastectomy when compared to those of lower income level as shown in Table 22.

Table 22 Predictors of prophylactic bilateral mastectomy

Model		B	Sig.	Odds Ratio	95% C I for EXP(B) Lower	Upper
	Constant	-1.380	.000	.252		
	Age 31-40	-.098	.995	.907	0.719	1.143
	Age 41-50	-.650	.408	.522	0.417	0.653
	Age 51-60	-.995	.000	.370	0.295	0.463
	Age 61-70	-1.741	.000	.175	0.139	0.221
	Age 71-80	-2.710	.000	.067	0.051	0.087
	Age greater than 80	-4.527	.000	.011	0.006	0.019
	Black	-.922	.000	.398	0.345	0.458
	Hispanic	-.405	.000	.667	0.584	0.762
	Asian or Pacific Islander	-.854	.050	.426	0.340	0.533
	Native American	-.720	.775	.930	0.566	1.528
	Other Race	-.425	.026	.654	0.522	0.819
	26th to 50th percentile	.148	.013	1.160	1.031	1.304
	51st to 70th percentile	.400	.000	1.491	1.327	1.664
	76th to 100th percentile	.432	.000	1.540	1.387	1.711

4.3.4 Relationship between type of mastectomy and disposition of patient (Hypothesis 4)

There is a significant association found between the disposition of patient and type of mastectomy. The large Chi-Square statistic (312.084) and its small significance level ($p<0.001$) indicate it is very unlikely that these variables are independent of each other. We thereby concluded that there is a relationship between type of mastectomy and disposition of patient as shown in Tables 23 and 24.

Table 23 Disposition of mastectomy patients

	Disposition of patient (uniform)							
	Routine	Transfer to short term hospital	Transfer other: includes skilled nursing facility	Home Health Care	Against Medical advise	Died in hospital	Discharged desitnation unknown	Total
Unilateral	31596	53	1649	9328	11	36	2	42675
Bilateral	10320	10	145	2497	0	6	1	12979
Total	41916	63	1794	11825	11	42	3	55654

Table 24 Disposition of patient and type of mastectomy

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	312.084	6	.000
Likelihood Ratio	372.760	6	.000
Linear-by-Linear Association	117.951	1	.000
N of Valid Cases	55654		

4.3.5 Relationship between total cost of mastectomy patients across race age or economic status (Hypothesis 5)

Assumption 1, dependent variables should be continuous. Total charges are continuous data. This assumption is accepted.

Assumption 2, two or more independent variables (categorical, numerical or ordinal); race, age, economic status are categorical variables. This assumption is accepted.

Assumption 3, independence of observations or independence of residuals. The value of Durbin-Watson for total charges should be between 1 and 3, or near to 2 to be accepted. The Durbin-Watson for total charges is 1.127 for mastectomy patients. This assumption is accepted.

Assumption 4, linear relationship between the dependent and independent variable(s): Significant relationships between dependent and independent variables existed based on significant correlations. This assumption is accepted.

Assumption 5, data must show homoscedasticity: Results indicated that the dots along the scatterplot are homogeneous and the same in distance along the linear fit line as shown in the Figure 25 above. This assumption is accepted.

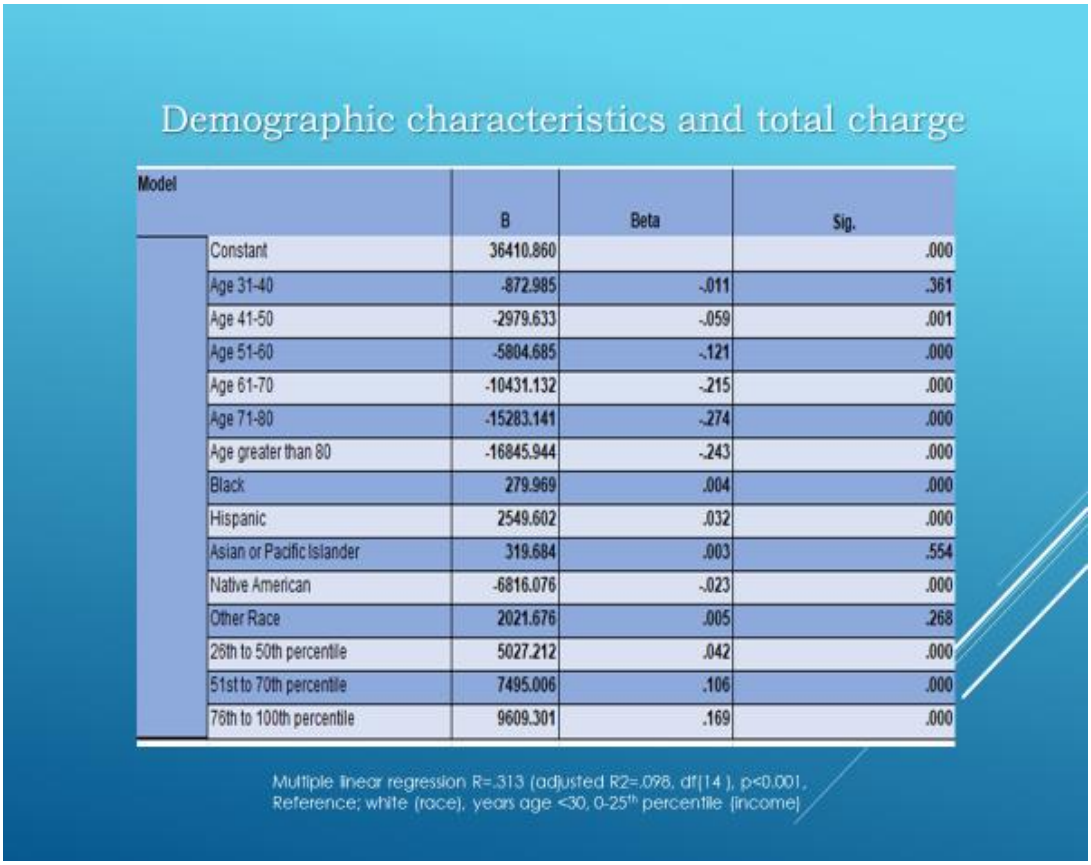
Assumption 6, data must not show multicollinearity: Using collinearity diagnostics, the VIF results must be less than 2 and will be ideal when close to 1. All results of VIF were less than 2, thus this assumption is accepted.

Assumption 7, no significant outliers: The cut point for the outliers while using Cook's distance is (4/n), which is equal to 0.000073. There were 2147 cases considered as outliers. These cases were excluded in the regression model.

Assumption 8, the residuals must be normally distributed: The residuals are normally distributed, as shown in Figure 25 above.

After accepting all assumptions for the total charges, the final model for the predictors of mastectomy patients are shown below in Table 25.

Table 25 Demographic Characteristics and total charge



4.3.6 Relationship between length of stay of mastectomy patients across race age and economic status (Hypothesis 6)

Assumption 1, dependent variables should be continuous. Length of stay are continuous data. This assumption is accepted.

Assumption 2, two or more independent variables (categorical, numerical or ordinal); race, age, economic status are categorical variables. This assumption is accepted.

Assumption 3, independence of observations or independence of residuals. The value of Durbin-Watson for total charges should be between 1 and 3, or near to 2 to be

accepted. The Durbin-Watson for length of stay is 1.721 for mastectomy patients. This assumption is accepted.

Assumption 4, linear relationship between the dependent and independent variable(s): Significant relationships between dependent and independent variables existed based on significant correlations. This assumption is accepted.

Assumption 5, data must show homoscedasticity: Results indicated that the dots along the scatterplot are homogeneous and the same in distance along the linear fit line as shown in the Figure 26 below. This assumption is accepted.

Assumption 6, data must not show multicollinearity: Using collinearity diagnostics, the VIF results must be less than 2 and will be ideal when close to 1. All results of VIF were less than 2, thus this assumption is accepted.

Assumption 7, no significant outliers: The cut point for the outliers while using Cook's distance is (4/n), which is equal to .00008379. There were 979 cases considered as outliers. These cases were excluded in the regression model (**47737-46758).**

Assumption 8, the residuals must be normally distributed: The residuals are normally distributed, as shown in Figure 26 below.

After accepting all assumptions for the length of stay, the final model for the predictors of mastectomy patients are shown below in Table 26.

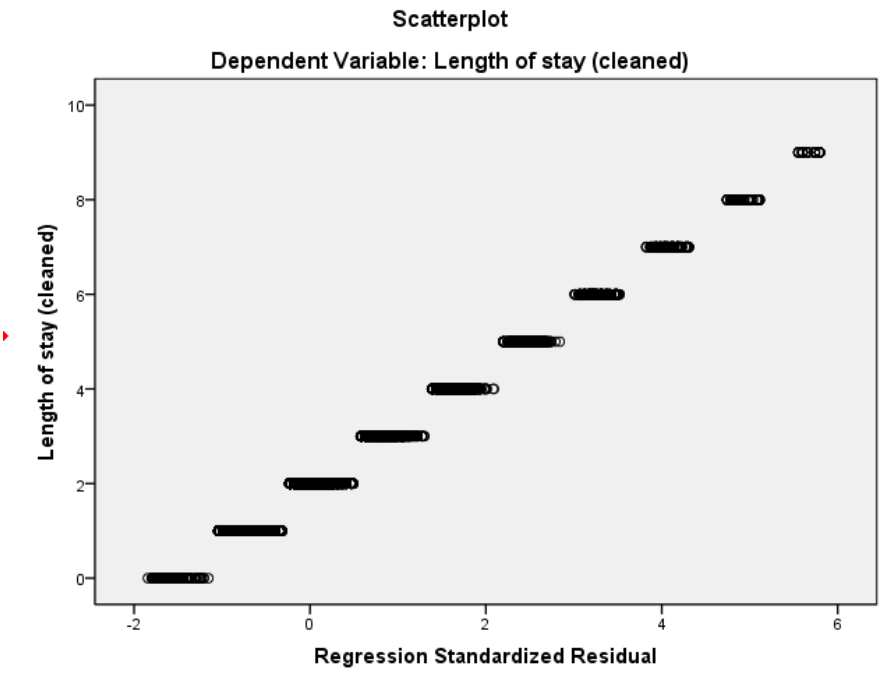
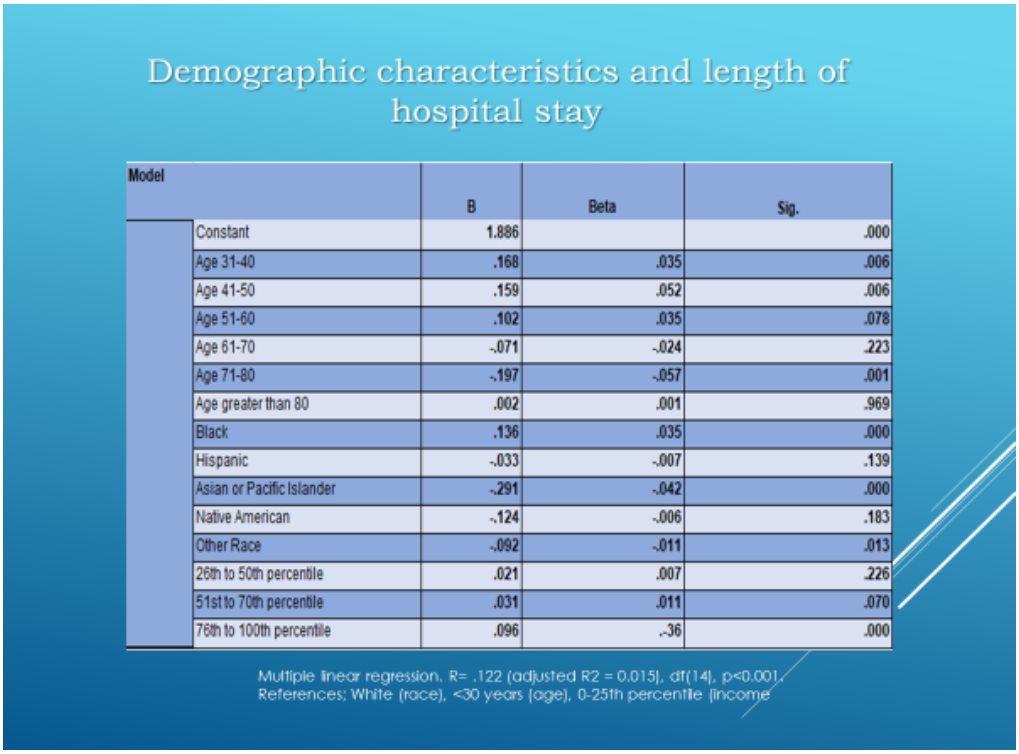


Figure 26 Length of Stay

Table 26 Demographic characteristics and length of stay



4.3.7 Relationship between total cost across various regions of the United States (Hypothesis 7) linear regression

Assumption 1, dependent variables should be continuous. Total Charges are continuous data. This assumption is accepted.

Assumption 2, two or more independent variables (categorical, numerical or ordinal); HOSP_REGION. This assumption is accepted.

Assumption 3, independence of observations or independence of residuals. The value of Durbin-Watson for total charges should be between 1 and 3, or near to 2 to be accepted. The Durbin-Watson for length of stay is 1.288 for mastectomy patients. This assumption is accepted.

Assumption 4, linear relationship between the dependent and independent variable(s): Significant relationships between dependent and independent variables existed based on significant correlations. This assumption is accepted.

Assumption 5, data must show homoscedasticity: Results indicated that the dots along the scatterplot are homogeneous and the same in distance along the linear fit line as shown in the figure 25 above. This assumption is accepted.

Assumption 6, data must not show multicollinearity: Using collinearity diagnostics, the VIF results must be less than 2 and will be ideal when close to 1. All results of VIF were less than 2, thus this assumption is accepted.

Assumption 7, no significant outliers: The cut point for the outliers while using Cook's distance is (4/n), which is equal to 0.000073. There were 2147 cases considered as outliers. These cases were excluded in the regression model.

Assumption 8, the residuals must be normally distributed: The residuals are normally distributed, as shown in Figure 25 above.

After accepting all assumptions for the total charges, the final model for the predictors of mastectomy patients are shown below in Table 27.

The region with highest costs for mastectomy patients was found in the West ($12,506.44) followed by northeast ($2,797.76). The region where the model indicated lower total charges was the Midwest (-$1,991.83). The region with the highest contribution of total charges is the West (beta=.158) followed by Northeast (.038).

The total charges= 32,690.47 (constant) + 2,797.76 (Northeast) – 1,991.83 (Midwest) + 12,506.44 (West).

Table 27 Total cost across hospital region

	B	Std. Error	Beta	t	Sig	Tolerance	VIF
(Constant)	32690.470	219.226		149.117	.000		
Northeast	2797.762	346.505	.038	8.074	.000	.789	1.267
Midwest	-1991.827	360.290	-.026	-5.528	.000	.799	1.252
West	12506.442	373.550	.158	33.480	.000	.808	1.237

R=.162, adjusted R^2=.026, df=3, p<0.001

4.2.8 Relationship between total cost across different hospital locations of the United States (Hypothesis 8)

Assumption 1, dependent variables should be continuous. Total Charges are continuous data. This assumption is accepted.

Assumption 2, two or more independent variables (categorical, numerical or ordinal); HOSP_REGION. This assumption is accepted.

Assumption 3, independence of observations or independence of residuals. The value of Durbin-Watson for total charges should be between 1 and 3, or near to 2 to be accepted. The Durbin-Watson for length of stay is 1.284 for mastectomy patients. This assumption is accepted.

Assumption 4, linear relationship between the dependent and independent variable(s): Significant relationships between dependent and independent variables existed based on significant correlations. This assumption is accepted.

Assumption 5, data must show homoscedasticity: Results indicated that the dots along the scatterplot are homogeneous and the same in distance along the linear fit line as shown in the Figure 25 above. This assumption is accepted.

Assumption 6, data must not show multicollinearity: Using collinearity diagnostics, the VIF results must be less than 2 and will be ideal when close to 1. All results of VIF were less than 2, thus this assumption is accepted.

Assumption 7, no significant outliers: The cut point for the outliers while using Cook's distance is (4/n), which is equal to 0.000073. There were 2147 cases considered as outliers. These cases were excluded in the regression model.

Assumption 8, the residuals must be normally distributed: The residuals are normally distributed, as shown in Figure 25 above.

After accepting all assumptions for the total charges, the final model for the predictors of mastectomy patients are shown below in Table 28.

Hospitals located in urban areas were found to decrease total costs (-$17,115.63)

The total charges= 36,995.29 (constant) – (17,115.63).

Table 28 Hospital location predictors of total charges

Model		Unstandardized Coefficients		Standardized Coefficients		
		B	Std. Error	Beta	t	Sig.
	(Constant)	36995.290	138.994		266.164	.000
	RURAL	-17115.631	444.138	-.164	-38.537	.000

R=.164, adjusted R^2=.027, df=1, p<0.001

4.3.9 Relationship between length of stay and payer (Hypothesis 9)

A One-way ANOVA was performed with Post Hoc Tests to show multiple comparison between LOS and the different payers. The mean LOS was 2.19 days as shown in Table 29. Medicare has a significantly lesser LOS than Medicaid. Medicaid has a significantly longer LOS than Medicare, private insurance and no-pay. Private insurance has a significantly less LOS than Medicaid and other insurance. Self-pay has a significantly longer LOS than no-pay as shown in Table 30 and Figure 27 below.

Table 29 Statistics length of stay

Statistics		
Parameter	Length of stay	Total charges
Mean	2.19	35252.70
Median	2.00	26759.00
Skewness	2.576	31077.039
Skewness	15.184	6.587
Std. Error of Skewness	.010	.010
Kurtosis	527.009	161.392

Table 30. One-way ANOVA multiple comparisons

Length of stay (cleaned)Bonferroni							
(I) Primary expected payer (uniform)		(J) Primary expected payer (uniform)	Mean Difference (I-J)	Std. Error	Sig.	Interval	
						Lower Bound	Upper Bound
	Medicare	Medicaid	-.142	.040	.005	-.26	-.03
		Private Ins.	.043	.023	.923	-.02	.11
		Self-pay	-.176	.095	.979	-.46	.10
		No-pay	.540	.188	.062	-.01	1.09
		Other	-.212	.074	.060	-.43	.00
	Medicaid	Medicare	.142	.040	.005	.03	.26
		Private Ins.	.185	.039	.000	.07	.30
		Self-pay	-.034	.100	1.000	-.33	.26
		No-pay	.682	.191	.005	.12	1.24
		Other	-.070	.080	1.000	-.30	.16
	Private Insurance	Medicare	-.043	.023	.923	-.11	.02
		Medicaid	-.185	.039	.000	-.30	-.07
		Self-pay	-.218	.095	.318	-.50	.06
		No-pay	.498	.188	.123	-.06	1.05
		Other	-.255	.073	.007	-.47	-.04
	Self-pay	Medicare	.176	.095	.979	-.10	.46
		Medicaid	.034	.100	1.000	-.26	.33
		Private Ins.	.218	.095	.318	-.06	.50
		No-pay	.716	.210	.010	.10	1.33
		Other	-.036	.118	1.000	-.38	.31
	No-pay	Medicare	-.540	.188	.062	-1.09	.01
		Medicaid	-.682	.191	.005	-1.24	-.12
		Private Ins.	-.498	.188	.123	-1.05	.06
		Self-pay	-.716	.210	.010	-1.33	-.10
		No-pay	-.752	.201	.003	-1.34	-.16
	Other	Medicare	.212	.074	.060	.00	.43
		Medicaid	.070	.080	1.000	-.16	.30
		Private Ins.	.255	.073	.007	.04	.47
		Self-pay	.036	.118	1.000	-.31	.38
		No-pay	.752	.201	.003	.16	1.34

The mean difference is significant level .05

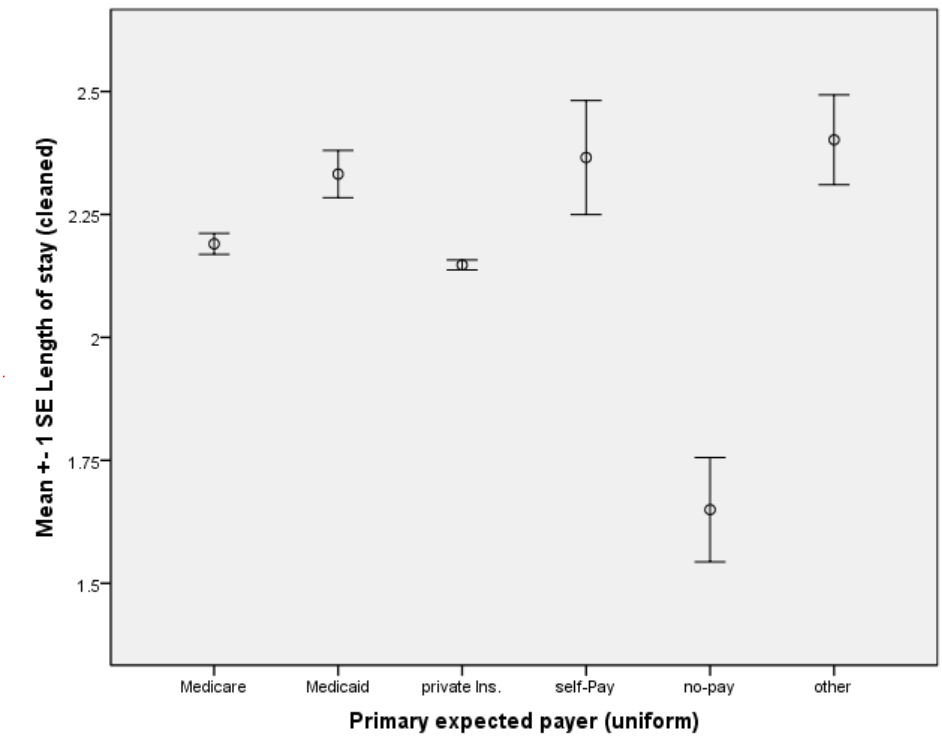


Figure 27 Means Plot LOS with Payer

4.3.10 Mortality and comorbidities (Hypothesis 10)

As part of the binary logistic regression, the data must pass the following six assumptions,

Assumption #1: dependent variable should be measured on a nominal level. This assumption is accepted.

Assumption #2: There are one or more independent variables that are continuous, ordinal or nominal (including dichotomous variables). This assumption is accepted.

Assumption #3: There are independence of observations. All subjects of dependent variable were different. This assumption is accepted.

Assumption #4: There should be no multicollinearity. Correlation was checked between independent variables. This assumption is accepted.

Assumption #5: There is a linear relationship. This assumption is accepted.

Assumption #6: There are no outliers. This assumption is accepted.

When analyzing the impact of comorbidities of mastectomy patients to the mortality rate, only those with significant results were illustrated in Table 31.

Fluid and electrolytes were the highest predictor of mortality with (24.086) followed by coagulopathy (7.457) and weight loss (6.202).

Table 31 Predictors of mortality for mastectomy patients

		B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I.for EXP(B)	
								Lower	Upper
	Metastatic Cancer	1.010	.355	8.088	1	.004	2.745	1.369	5.506
	Weight Loss	1.825	.462	15.632	1	.000	6.202	2.510	15.326
	Coagulopathy	2.009	.439	20.917	1	.000	7.457	3.152	17.640
	Fluid & Electrolyte Disorders	3.182	.360	78.003	1	.000	24.086	11.889	48.798
	Constant	-8.175	.245	1113.023	1	.000	.000		

CHAPTER V

DISCUSSION

5.1 Discussion

5.1.1 Introduction

This data from the current study highlights the outcomes associated with mastectomy patients admitted to hospitals in the United States from 2008 through 2011. The purpose of this study was to determine the impact of socio-demographic characteristics as predictors of length of stay, total charges and mortality for patients electing mastectomy. The study revealed predictors and study outcomes which highlighted significant racial and socio-economic disparities among the mastectomy population. While the decision to undergo mastectomy is often patient driven, the weight of this decision is placed on our healthcare system and insurance providers to assume the financial burden.

5.1.2 Sociodemographic characteristics and medical information

The data for this study was obtained from the HCUP NIS database for evaluation of socio-demographic and medical information as predictors of length of hospital, total charges and mortality. Total charges for unilateral and bilateral mastectomy increased proportionately each year of the study. There were 56,676 male and female mastectomy patients extracted from NIS HCUP dataset. For purposes of this study, male patients were excluded, leaving 55,781 female mastectomy patients admitted during the years 2008 through 2011. Descriptive statistics were used to measure frequency. The mean age of the study population was (59.23). The highest number of cases of unilateral mastectomy occurred in women aged (51-70). The highest number of cases of bilateral

mastectomy occurred in women aged (41-50) and with private insurance (50.5%) and Medicare (36.8%).

There were significant relationships between mastectomy patients and type of comorbidity. The highest incidence was observed with patients who had hypertension (41.7%), diabetes uncomplicated (13.4%), chronic pulmonary disease (11.5%), hyperthyroidism (11.2%) and metastatic cancer (10.3%) and others. Hypertension and diabetes showed the highest incidence as reported by Abdelhamid et al., which supports the results of this study. [63] The lowest incidences occurred with acquired immune deficiency syndrome (.02%), drug abuse (0.3%), chronic blood loss anemia (0.4%), alcohol abuse (0.4%) and others.

5.1.3 Mortality rate

The association between race and inpatient death was expected as research and previous literature revealed that Black women experienced a higher rate of mortality than White women. [64]The overall incidence in mortality for mastectomy patients is low. The mortality rate for mastectomy patients in this study was (.1%) as shown in Table 10. There were only 43 reported deaths among the 55,781 mastectomy patients during the years 2008 through 2011. When normalized by race, Blacks had the highest mortality in 2008 (0.025%), 2009 (0.019%) and 2011 (0.016%). A study conducted by Akinyemiju et al. showed privately insured Black patients were more likely to experience post-surgical complications and higher hospital mortality compared with White patients. [65] Additional findings which also support the results of this study were presented in a study conducted by The Ohio State University (OSU). This study revealed the challenges for African American women. The OSU study concluded that lack of health education and awareness

are the leading causes of morbidity and mortality among the African American women. The authors of this study state that for a woman to take preventative health measures, they must be aware that such prevention options exist.[66]

5.1.4 Length of hospital stay

The mean hospital length of stay remained consistent among the mastectomy population with an average length of stay 2.1 days. Patients who elected immediate reconstruction stayed an additional .397 days. This value compared to the findings by Wang et al. where length of stay was 2.32 to 2.84 days based on type of reconstruction performed.[67] Comparisons among the different payers revealed Medicare had a significantly lesser length of stay than Medicaid. Medicaid had a significantly longer length of stay than Medicare, private insurance and no-pay. Private insurance had a significantly lesser length of stay than Medicaid and other insurance with self-pay having a significantly longer length of stay than no-pay.

Medicare Part A covers inpatient hospitalization. A patient must cover their Part A deductible before Medicare will begin coverage of hospital stay and a $0 coinsurance for days 1-60 for each benefit period.

5.1.5 Hospital stay and total charges

The mean total charges for the current study was $35,303.76. This finding is similar to the findings of Smith et al. ($26,399 and $36,367), respectively. These variations in cost of total charges are due to type of mastectomy (unilateral-bilateral) and whether the patient elected immediate reconstruction. [68] Patients age 61-80 have significantly lower total charges than those less than 30. This could be due to type mastectomy performed

(unilateral vs. bilateral). Hispanics and Blacks had significantly higher total charges than Whites.

Mastectomy in-patients in the Western region had significantly higher charges than those in other regions. These finding were consistent with the findings of Alexandra Bucknor et al. Additionally, patients treated in rural hospitals had significantly lower hospital charges than those treated in urban hospitals. [69]

5.1.6 Median household income

The median household income showed similar values across the four quartiles when analyzing only the mastectomy universe. When we looked at normalized the ratios with total number of discharges by income and race, Whites and Asians had the highest income in 2008, 2009 and 2011 ($64,000+). In 2009, Whites had the highest income across all four income quartiles. The normalized ratios with total number of discharges by race across the four years showed Whites and Asians had the highest number of discharges from 2008 through 2011 with Asians dominating in 2008 and 2011 with (.39%) and (.43%) respectively. These findings are consistent with the 2020 U.S. Census bureau. The Census bureau reported the average income for Asian Americans is among the highest in America. For 2020, the median Asian American household income is approximately $80,000, compared to the median U.S. household income of approximately $64,000.00.

5.1.7 Comorbidities and total charges

The control of fluid collection at the surgical site is critical to the prevention of tissue necrosis and wound infection. The findings of a study conducted by Suh et al. revealed the dangers of fluid imbalance and seroma formation leading to wound infection which

may necessitate an additional surgical involvement and increased hospital stay [70]. In the present study, several comorbidities affected total charges among the mastectomy population, fluid and electrolyte disorders had the greatest impact on total charges, causing an increase of ($11,551.14) and weight loss by ($6,770.66), anemia ($4,550.00), obesity ($3,650.56) and depression ($861.44).

5.1.8 Mastectomy reconstruction and insurance

This study examined health insurance coverage, race/ethnicity and mastectomy and reconstruction rates among women who underwent mastectomy whether for risk reduction or disease presence. The results revealed Blacks and Hispanics women had a lower rate of mastectomy than White women. Type of insurance significantly impacted reconstruction. Women with private insurance were more likely to undergo reconstruction than women insured by Medicare. A study conducted by Akinyemiju et al. revealed Black women were less likely to elect mastectomy compared with White women regardless of type of insurance.

To determine predictors for immediate reconstruction post-mastectomy, several independent factors were evaluated for significance. Patients who underwent immediate reconstruction were younger and more likely to be White. Patients less likely to undergo reconstruction were likely to have comorbidities and Medicare as their primary insurance. The payer predictor of immediate reconstruction was private insurance. These findings were similar to that of Reuben et al. where payer predictor of immediate reconstruction was private insurance or HMO coverage. There are others that also confirmed these findings. [7172]

5.1.9 Race Ethnicity and preventative screening

The Breast Cancer Surveillance Consortium (BCSC) is a network of breast cancer registries that collect and analyze data on breast cancer screening and outcomes conducted in the United States. The important objectives of the BCSC are to analyze the breast cancer screening to improve mammography screening practices.

According to BCSC, there were a total of 11,220,200 mammograms performed from 1996 through 2016. An analysis by race of mammograms performed during this period revealed the highest percentage of mammograms were performed on Whites (73.2%), Blacks (10.8%), Asians (9.2%) and Hispanic (4.8%). [73]The findings of this analysis indicate that insufficient mammography screening may be a contributing factor to the serious disease revealed in the Black population.

5.2 Study limitations

The main limitations of this study are related to the use of a National Inpatient Sample. The National Inpatient Sample provides benefits but does impose limitations. The consolidation of information into one large United States database provides valuable information on current medical practices. However, the accuracy of the data relies on information being entered and coded correctly by the practitioner. Coding errors as well as missing data can result in data that is difficult to interpret, producing inaccurate analysis. The 2008 through 2011 dataset utilizes ICD-9 codes which are broad for many diagnoses and procedures. Due to the broad nature of specific codes, the ability to utilize specific diagnoses and/or procedures during the patient encounter can be limited. Additionally, the NIS contains a snapshot of the inpatient encounter, and patient information is reported at discharge level. There is no information contained in the

dataset on post-surgical outcomes. While the beginning stages of reconstruction may occur during the inpatient encounter, the data related to delayed reconstruction, if elected is not captured in this dataset.

The NIS contains not only clinical but also resource use information and does not include the psychological information of the patient relating to the impact of mastectomy as well as overall satisfaction. Ideally, having post-surgical data that occurs within 30 to 60 days post discharge would provide useful information regarding complications, overall decision satisfaction as well as any increases in total charges.

CHAPTER VI

CONCLUSION AND CONTINUED RESEARCH

6.1 Study summary

This study highlighted hospitalization characteristics related to female mastectomy admissions in the United States between 2008 and 2011. Important information was revealed regarding length of stay, mortality and insurance. The outcomes of this study revealed information about health status, financial status and mortality. There were two types of variables utilized in this study- independent and dependent variables. Length of stay, total charges and mortality are considered dependent variables. Sociodemographic characteristics and health information are considered independent variables. The sociodemographic characteristics included were age, race, type of insurance and income status. In addition to sociodemographic characteristics, information related to patient health included, comorbidities (number and type), type of reconstruction and type of mastectomy. The total number of patients who elected mastectomy during the years 2008 through 2011 was 55,781. Approximately (65%) of the women were White. There were 895 men excluded from this study.

Both descriptive and inferential statistics were used in this study for purposes of data analysis. Inferential statistics were used to make predictions or inferences about the mastectomy population. The inferential statistics used in this study included, multiple linear regression, binomial logistic regression, one-way ANOVA and Chi-Square. Descriptive statistics were used to summarize information about the variables in the dataset.

An examination of racial and socioeconomic differences among the mastectomy universe showed that White women and Asian women had the highest number of discharges during the four years of this study. While income appears to be equally distributed, a further analysis of income quartiles across race again revealed White women and Asian women were in the highest income quartile each year. The comorbidities that increased total charges were fluid and electrolyte disorders, weight loss followed by anemia. Immediate reconstruction was low among the Black, Hispanic and Asian races. Patients electing immediate reconstruction stayed an average of .397 days longer than those that did not elect reconstruction. White women were more likely to have private insurance and Medicare. While mortality was low among the mastectomy population normalized ratios revealed Black women had the highest incidence of mortality.

The Breast Cancer Surveillance Consortium analyzed the breast cancer screening practices across race. Black women were noted as having inadequate mammography screening compared to White women. This important statistic could support the argument that insufficient screening could be a contributing factor leading to more serious disease and increased in-patient mortality within the Black population.

While health policies focus on bringing healthcare to those in need, access to care is only effective if there is a solid foundation of health education to better guide health related behavior. This begs the question of how to better educate to improve the medical wellness of American families. The continued push by lawmakers to provide economic subsidies may not be the answer. The most basic component of socioeconomic status is education. An educated person can develop the skills and resources to promote health and well-being. Policies promoting better early childhood health education, while

simplistic, may have a sizeable effect on health-related behaviors to promote better health outcomes.

6.2 Future research

While the HCUP dataset does provide discharge data for a specific patient encounter, the information is at discharge level. There is a need for future research to include post-surgical outcomes for patients electing mastectomy with or without reconstruction. Additionally, longitudinal studies are needed to provide patient data to include, surgical complications, hospital readmissions and overall patient satisfaction. The current study is only a snapshot of total charges related to a single in-patient mastectomy encounter and is lacking critical information that may impact the overall total costs of this elective procedure.

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