

Trends in utilization of contralateral prophylactic mastectomy among different age, racial and ethnic groups

Nicci Owusu-Brackett¹, Jessica Aduwo¹, Theresa S. Relation², Oindrila Bhattacharyya³, Yaming Li⁴, James L. Fisher⁵, Bridget A. Oppong¹

¹Division of Surgical Oncology, Department of Surgery, The Ohio State University Wexner Medical Center and James Cancer Hospital, Columbus, OH, USA; ²Department of Surgery, MetroHealth Systems Case Western Reserve University, Cleveland, OH, USA; ³Comprehensive Cancer Center, The Ohio State University, Columbus, OH, USA; ⁴Department of Biomedical Informatics, University of Pittsburgh, Pittsburgh, PA, USA; ⁵James Cancer Hospital and Solove Research Institute, Columbus, OH, USA

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Correspondence to: Bridget A. Oppong, MD. Division of Surgical Oncology, Department of Surgery, The Ohio State University Wexner Medical Center and James Cancer Hospital, 410 W. 10th Ave., Columbus, OH 43210, USA. Email: bridget.oppong@osumc.edu.

Background: The use of contralateral prophylactic mastectomy (CPM) has increased over the last two decades with variations in the frequency of reconstruction. The objective of this cohort study is to elucidate the use of CPM and reconstruction among underrepresented racial and ethnic groups and women over 65 years.

Methods: Women over 18 years, diagnosed with stages I to III breast cancer who underwent mastectomy from 2004–2017 were identified in the National Cancer Database (NCDB) and grouped into CPM vs. non-CPM. Multivariable analyses were used to examine the associations between CPM and reconstruction with sociodemographic and clinical factors.

Results: A total of 571,649 patients were identified. Patients who underwent CPM were under 50 years (45.9%), White (88.4%) and with private insurance (73.5%). On multivariable analysis, women over 65 years [odds ratio (OR): 0.18, P<0.001], non-White (Black, OR: 0.56, P<0.001) and without private insurance (uninsured, OR: 0.50, P<0.001) had decreased odds of CPM. Women over 65 years (OR: 0.11, P<0.001), non-White (Asian/Pacific Islander, OR: 0.58, P<0.001) and without private insurance (Medicaid, OR: 0.41, P<0.001) had decreased odds of reconstruction.

Conclusions: Non-White women and women over the age of 65 years were less likely to have CPM or reconstruction than their White counterparts from 2004 to 2017. Research is needed to understand factors impacting decision-making.

Keywords: Breast cancer; contralateral prophylactic mastectomy (CPM); breast reconstruction

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Introduction

The American Cancer Society estimates 287,850 new cases of invasive breast cancer in the US for 2022 with 43,250 deaths due to breast cancer (1). A proportion of 2–11% of women with unilateral breast cancer develop contralateral breast cancer (2). With the increasing incidence of breast cancer, there has been a growing focus on cancer prevention. As a result, we have seen increased usage of bilateral prophylactic mastectomy for risk reduction (3). Controversy exists regarding whether contralateral prophylactic mastectomy (CPM) is performed too often; however, due to patient perception of risk, desire for

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increased symmetry, increased usage of germline testing or surgeon preference, an increasing trend of bilateral mastectomies has been noted in the US.

The use of CPM has been previously associated with tumor characteristics, patient age and patient race (4). Studies have consistently shown higher proportion of usage among non-Hispanic White women compared to women of other ethnicities (3,5,6). Furthermore, Black women have a higher proportion of estrogen receptor (ER)⁻/progesterone receptor (PR)⁻ tumors, which have been shown to be more aggressive with a 1.6-fold increased risk of developing contralateral breast cancer compared to ER⁺/PR⁺ tumors (7,8). Therefore, it is unclear if the demonstrated disparity of CPM usage and race may be confounded by ER/PR status. While differences in CPM usage by race have been shown, differences in usage by patient age have not been thoroughly evaluated.

Breast reconstruction aims to recreate breast contour, nipple and areola as well as optimize symmetry between both breasts. Autologous reconstructions deliver a more natural-appearing reconstruction with consistency more similar to natural breasts compared to implant-based reconstruction (9,10). Studies have shown decreased anxiety after CPM and higher satisfaction with breasts among patients who underwent bilateral mastectomy with breast reconstruction (11-14). Furthermore, autologous reconstruction is associated with fewer long-term sequelae and higher long-term quality of life (9,10). The significant impact of breast reconstruction postmastectomy resulted in incorporation of preoperative breast reconstruction consultations into breast cancer management guidelines.

The Women's Health Cancer Rights Act of 1998 ensured

Highlight box

Key findings

• Race and age of patients play a role in access to contralateral prophylactic mastectomy (CPM) and breast reconstruction.

What is known and what is new?

- Differences in CPM usage by race have been shown.
- Decreased access to and frequency of CPM and breast reconstruction for non-White women and women over the age of 65 years.

What is the implication, and what should change now?

• Access to CPM and reconstruction needs to be improved for non-White women and women over 65 years. Discussion of CPM and breast reconstruction should be standardized to ensure that all patients have access to all treatment options for breast cancer.

that insurance covered access to breast reconstruction (15). As a result, the number of immediate breast reconstructions (IBRs) has increased, specifically implant-based reconstruction has increased more than autologous (16). However, prior studies have suggested that disparities exist in access to CPM (15,17). Brown et al. [2016] reported lower proportion of CPM usage in Black, Hispanic and Asian/ Pacific Islander patients compared to White patients (18). Our study compared the use of CPM and different types of breast reconstruction among typically underrepresented racial and ethnic groups as well as women over the age of 65 to elucidate the etiology of suggested disparities in access to CPM and to evaluate whether disparities exist in access to breast reconstruction. We present this article in accordance with the STROBE reporting checklist (available at https:// gs.amegroups.com/article/view/10.21037/gs-22-759/rc).

Methods

Description of data source

The National Cancer Database (NCDB) is a joint American College of Surgeons and Commission on Cancer clinical oncology database drawn from hospital registry data collected in more than 1,500 facilities (19). For this study, the NCDB was used. The database was queried for female cases over the ages of 18 years with stages I-III breast cancer who underwent mastectomy between 2004 and 2017. Male cases were excluded due to low incidence. The data used in the study are derived from a de-identified NCDB file. Sociodemographic and clinical variables of patients diagnosed with breast cancer were obtained. This study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The Ohio State University Office of Responsible Research Practices deemed this study Institutional Review Board (IRB)-exempt. Informed consent was not required due to the retrospective nature of this study.

Statistical analysis

The cohort study was divided into CPM and non-CPM. Sociodemographic variables, clinical characteristics, and treatment (surgery, chemotherapy, and radiation therapy) were tabulated as frequencies for categorical variables and means with standard deviations for continuous variables. On bivariable analysis, the Chi-squared test, Student's *t*-test, and analysis of variance (ANOVA) were used, as appropriate, to compare sociodemographic, clinical, and

Variables	Subcategories	Total (n=571,649), n (%)	Non-CPM (n=409,081), n (%)	CPM (n=162,568), n (%)	P value
Age (years)	<40	43,222 (7.6)	21,451 (5.2)	21,771 (13.4)	<0.001
	41–50	126,923 (22.2)	74,001 (18.1)	52,922 (32.6)	
	51–65	209,962 (36.7)	147,348 (36.0)	62,614 (38.5)	
	>65	191,542 (33.5)	166,281 (40.6)	25,261 (15.5)	
Insurance	Private	314,332 (56.0)	195,829 (48.9)	118,503 (73.5)	<0.001
	Medicare	194,555 (34.6)	165,046 (41.2)	29,509 (18.3)	
	Medicaid	40,446 (7.2)	29,778 (7.4)	10,668 (6.6)	
	Uninsured	12,179 (2.2)	9,664 (2.4)	2,515 (1.6)	
Race	White	481,191 (84.2)	337,551 (82.5)	143,640 (88.4)	<0.001
	Black	65,977 (11.5)	52,115 (12.7)	13,862 (8.5)	
	Asian/Pacific	24,481 (4.3)	19,415 (4.7)	5,066 (3.1)	
Hispanic	No	517,677 (94.3)	368,347 (93.9)	149,330 (95.2)	<0.001
	Yes	31,300 (5.7)	23,770 (6.1)	7,530 (4.8)	
Year of	2004–2010	208,114 (36.4)	164,152 (40.1)	43,962 (27.0)	<0.001
diagnosis	2011–2017	363,535 (63.6)	244,929 (59.9)	118,606 (73.0)	
Clinical stage	I	263,372 (46.1)	184,121 (45.0)	79,251 (48.8)	<0.001
	II	230,459 (40.3)	165,950 (40.6)	64,509 (39.7)	
	Ш	77,806 (13.6)	59,001 (14.4)	18,805 (11.6)	
Breast cancer	ER⁺/HER2⁻	265,949 (68.1)	185,019 (69.6)	80,930 (64.7)	<0.001
subtypes	HER2⁺	68,239 (17.5)	44,605 (16.8)	23,634 (18.9)	
	ER ⁻ /PR ⁻ /HER2 ⁻	56,545 (14.5)	36,042 (13.6)	20,503 (16.4)	

Table 1 Comparison of sociodemographic and clinical factors in study population

Data regarding insurance status, Hispanic race, clinical stage and breast cancer subtype were not available for all cases. CPM, contralateral prophylactic mastectomy; ER, estrogen receptor; HER2, human epidermal growth factor receptor 2; PR, progesterone receptor.

treatment factors between CPM and non-CPM patients.

A multivariable model was used to determine the impact of age and race on CPM and reconstruction as well as the type of reconstruction. Other covariates analyzed included insurance, year of diagnosis, clinical stage, breast cancer subtypes, facility type, facility location, clinical stage, comorbidities and the use of chemotherapy or radiation. The multivariate model was built by inclusion of all significant variables from a bivariate analysis and a backward stepwise variable elimination method was performed using 0.1 as the significance level to remain in the model. All tests were two-sided, and a P value of <0.05 was considered statistically significant. The statistical analysis was performed using Stata software version 17.0 (Stata Corporation, College Station, TX, USA) and R version 3.6.0.

Results

CPM

There were 571,649 women in the NCDB with nonmetastatic breast cancer who underwent definitive surgery between 2004 and 2017. The overall frequency of CPM was 28.4% during the period studied. Between 2004–2010, the overall frequency was 21.2%, and this increased to 32.6% between 2011–2017 (*Table 1*). The frequency of CPM increased each year across all racial and ethnic groups as well as for women over the age of 65 years (*Figure 1*).

On bivariable analysis, patients who were younger, White and had private insurance were more likely to undergo CPM (*Table 1*). CPM was more likely among younger women with frequency declining with each



Figure 1 Rates of CPM in women. CPM, contralateral prophylactic mastectomy; NHW, non-Hispanic White; NHB, non-Hispanic Black.

factors associated with CPM				
Variables	Cubastagarias	CPM		
variables	Subcategories -	OR (95% CI)	P value	
Age (years)	<40	Ref.		
	41–50	0.69 (0.67–0.71)	<0.001	
	51–65	0.40 (0.39–0.41)	<0.001	
	>65	0.18 (0.17–0.18)	<0.001	
Insurance	Private	Ref.		
	Medicare	0.72 (0.71–0.74)	<0.001	
	Medicaid	0.65 (0.63–0.67)	<0.001	
	Uninsured	0.50 (0.47–0.53)	<0.001	
Race	White	Ref.		
	Black	0.56 (0.55–0.58)	<0.001	
	Asian/Pacific	0.46 (0.44–0.47)	<0.001	
Hispanic	No	Ref.		
	Yes	0.61 (0.60–0.64)	<0.001	
Year of	2004–2010	Ref.		
diagnosis	2011–2017	1.51 (1.48–1.55)	<0.001	
Clinical stage	I	Ref.		
	II	0.81 (0.80–0.83)	<0.001	
	III	0.69 (0.67–0.71)	<0.001	
Breast cancer	ER*/HER2-	Ref.		
subtypes	HER2⁺	1.04 (1.02–1.07)	<0.001	
	ER ⁻ /PR ⁻ /HER2 ⁻	1.22 (1.20–1.25)	<0.001	

Table 2 Multivariable analysis of sociodemographic and clinicalfactors associated with CPM

CPM, contralateral prophylactic mastectomy; OR, odds ratio; CI, confidence interval; Ref., reference; ER, estrogen receptor; HER2, human epidermal growth factor receptor 2; PR, progesterone receptor.

decade of life from 32.6% for women between the ages of 41 and 50 years to 15.5% for women over the age of 65 years (P<0.001). Similarly, White women were more likely to undergo CPM at a proportion of 88.4% compared to 4.8% for Hispanic women, 8.5% for Black women and 3.1% for Asian/Pacific Islander women (P<0.001). Insurance status was also noted to be related to the CPM proportion at 73.5% for patients with private insurance compared to 6.6% for Medicaid patients, 1.6% for patients without insurance and 18.3% for Medicare patients (P<0.001).

Multivariable analysis (*Table 2*) demonstrated increased odds of CPM significantly associated with young patient age, White race/ethnicity, private insurance status, early clinical stage, hormone receptor positive breast cancer subtype and recent year of diagnosis. The analysis revealed decreased odds of CPM associated with age greater than 65 years [odds ratio (OR): 0.18, P<0.001] compared to women under the age of 40 years, the population with the highest proportion. Decreased odds of CPM were also associated with Asian/Pacific Islander (OR: 0.46, P<0.001), Black (OR: 0.56, P<0.001) and Hispanic race/ethnicity (OR: 0.61, P<0.001) compared to White women. In addition, decreased odds of CPM were associated with lack of insurance (OR: 0.50, P<0.001), Medicaid (OR: 0.65, P<0.001) and Medicare (OR: 0.72, P<0.001).

Advanced clinical stage and hormone receptor positive breast cancer subtype were associated with decreased odds of CPM. Patients with stage III disease had decreased odds of undergoing CPM (OR: 0.69, P<0.001) compared to patients with stage I disease. Furthermore, patients with triple negative breast cancer (OR: 1.22, P<0.001) and human epidermal growth factor receptor 2 (HER2)⁺ breast

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Variables	Subcategories	No reconstruction (n=85,972), n (%)	Tissue (n=28,340), n (%)	Implant (n=39,172), n (%)	Combined (n=9,084), n (%)	P value
Age (years)	<40	9,026 (10.5)	4,499 (15.9)	6,669 (17.0)	1,577 (17.4)	<0.001
	41–50	22,843 (26.6)	11,086 (39.1)	15,473 (39.5)	3,520 (38.7)	
	51–65	34,479 (40.1)	10,687 (37.7)	14,079 (35.9)	3,369 (37.1)	
	>65	19,624 (22.8)	2,068 (7.3)	2,951 (7.5)	618 (6.8)	
Race	White	75,499 (87.8)	24,731 (87.3)	35,197 (89.9)	8,213 (90.4)	<0.001
	Black	7,679 (8.9)	2,733 (9.6)	2,766 (7.1)	684 (7.5)	
	Asian/Pacific	2,794 (3.2)	876 (3.1)	1,209 (3.1)	187 (2.1)	
Hispanic	No	78,761 (95.4)	25,915 (94.5)	36,182 (95.0)	8,472 (96.2)	<0.001
	Yes	3,795 (4.6)	1,495 (5.5)	1,906 (5.0)	334 (3.8)	
Insurance	Uninsured	1,711 (2.0)	297 (1.1)	444 (1.1)	63 (0.7)	<0.001
	Insured	54,845 (64.4)	23,625 (84.0)	32,420 (83.3)	7,613 (84.3)	
	Medicaid	6,503 (7.6)	1,497 (5.3)	2,184 (5.6)	484 (5.4)	
	Medicare	22,052 (25.9)	2,693 (9.6)	3,889 (10.0)	875 (9.7)	
Year of diagnosis	2004–2010	26,546 (30.9)	6,923 (24.4)	8,631 (22.0)	1,862 (20.5)	<0.001
	2011–2017	59,426 (69.1)	21,417 (75.6)	30,541 (78.0)	7,222 (79.5)	

Table 3 Type of reconstruction among patients with CPM

Data regarding Hispanic race and insurance status were not available for all cases. CPM, contralateral prophylactic mastectomy.

cancer (OR: 1.04; P<0.001) had increased odds of CPM compared to $ER^+/HER2^-$ subtype (P<0.01).

Breast reconstruction after CPM

A total of 76,596 women underwent reconstruction following CPM from 2004 to 2017. A total of 28,340 women had tissue reconstruction while 39,172 women had implant and 9,084 women had a combination. The overall frequency of reconstruction during this period was 47.1%, which increased from 39.6% between 2004 to 2010 to 49.9% from 2011 to 2017. This increase was statistically significant (P<0.001). Reconstruction with implant was more common than tissue or combined reconstruction at a frequency of 24% compared to 17.4% and 5.6%, respectively (*Table 3*).

On bivariate analysis, patients who were younger, White and had private insurance were more likely to undergo reconstruction. Reconstruction following CPM was more likely among younger women with frequency declining with each decade of age of increase of the patient. The frequency for reconstruction was 58.5% for women under the age of 40 years to 22.3% for women over the age of 65 years (P<0.001). Similarly, White women were more likely to undergo reconstruction at 47.4% compared to 44.6% for Black women and 44.8% for Asian/Pacific Islander patients (P<0.001). Furthermore, insurance status was also noted to be related to the frequency of breast reconstruction at 53.7% for patients with private insurance compared to 25.3% for patients with Medicare, 32% for patients without insurance and 39% for patients with Medicaid (P<0.001). The percentages mentioned here are obtained by adding the percentages of three columns in *Table 3*—reconstruction with tissue, reconstruction with implant and combined reconstruction, corresponding to each variable.

Multivariable analysis of reconstruction demonstrated decreased odds associated with older age, non-White race/ ethnicity, non-private insurance, advanced clinical stage hormone receptor positive breast cancer subtype and use of radiation therapy (*Table 4*). Patients over the age of 65 years had decreased odds of reconstruction compared to women under the age of 40 years, the population with the highest frequency (OR: 0.11, P<0.001). Asian/Pacific Islander (OR: 0.58, P<0.001), Black (0.73, P<0.001) and Hispanic women (0.86, P<0.001) had decreased odds of reconstruction compared to White women (P<0.001). Other important factors leading to decreased odds of reconstruction were

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 Table 4 Multivariable analysis of sociodemographic and clinical factors associated with reconstruction

Variables	Subastagorias	Reconstruction		
variables	Subcategories -	OR (95% CI)	P value	
Age (years)	<40	Ref.		
	41–50	0.73 (0.71–0.75)	<0.001	
	51–65	0.35 (0.34–0.36)	<0.001	
	>65	0.11 (0.11–0.12)	<0.001	
Insurance	Private	Ref.		
	Medicare	0.45 (0.44–0.46)	<0.001	
	Medicaid	0.41 (0.40–0.42)	<0.001	
	Uninsured	0.27 (0.25–0.28)	<0.001	
Race	White	Ref.		
	Black	0.73 (0.72–0.75)	<0.001	
	Asian/Pacific	0.58 (0.56–0.61)	<0.001	
Hispanic	No	Ref.		
	Yes	0.86 (0.83–0.89)	<0.001	
Year of	2004–2010	Ref.		
diagnosis	2011–2017	1.61 (1.57–1.65)	<0.001	
Clinical stage	I	Ref.		
	П	0.69 (0.68–0.70)	<0.001	
	III	0.36 (0.35–0.37)	<0.001	
Breast cancer	ER⁺/HER2⁻	Ref.		
subtypes	HER2⁺	0.88 (0.86–0.90)	<0.001	
	ER ⁻ /PR ⁻ /HER2 ⁻	0.76 (0.75–0.78)	<0.001	

OR, odds ratio; CI, confidence interval; Ref., reference; ER, estrogen receptor; HER2, human epidermal growth factor receptor 2; PR, progesterone receptor.

lack of insurance (OR: 0.27, P<0.001), Medicaid (OR: 0.41, P<0.001) or Medicare insurance (OR: 0.45, P<0.001) as well as hormone receptor negative breast cancer subtype (OR: 0.76, P<0.001) and use of radiation therapy (P<0.001).

Discussion

In examination of cases reported to the NCDB, women who underwent CPM with subsequent reconstruction were more likely to be White, young, with private insurance, early stage of disease and not require radiation therapy. Our findings demonstrate that there are differences in the use of CPM and reconstruction between White women and non-White women as well as younger and older women (3,4,20,21). Similar to prior studies, non-Hispanic White women had the highest usage of CPM and reconstruction followed by Hispanic, Black and then Asian/Pacific Islander women. Research has shown that regardless of ER/PR status and tumor stage, CPM usage differs by race. Using the Surveillance, Epidemiology, and End Results (SEER) 18 database, a study by Brown et al. [2016] that stratified racial/ethnic differences by ER/PR status determined that White women had the highest CPM usage compared to Black women (18). The study discovered that for ER⁺/ PR⁺ breast cancer, age-adjusted CPM usage was 20.2% for White women and 10.4% for Black women. However, for ER⁻/PR⁻ breast cancer, the CPM usage was 18% for White women and 8.6% for Black women. Reasons for these differences are unclear.

Does receipt of reconstruction impact CPM?

Our study demonstrates that women under the age of 40 years have the highest proportion of CPM and reconstruction followed by women ages 41-50 years then 51-65 years and finally women over the age of 65 years. Our study confirms that Black and Hispanic women are less likely to receive IBR compared to White women (22,23). Butler et al. [2016] found an IBR frequency of 35.2% for White women compared to 33.3% for Hispanic women and 24.6% for Black women (24). Previous reports indicated that the percentages of CPM in patients aged 65 years or older were higher in those who had mastectomy and IBR (27.4%) compared to patients who had mastectomy without IBR (9.8%) (25-27). Furthermore, the frequency of mastectomy and IBR was lower in patients aged 65 years or older (27.4%) compared to patients younger than 65 years (45.9%) (25). We hypothesize that access to reconstruction may play a role in a patient's decision to pursue risk-reducing surgery; however, given that our study only evaluated frequency of reconstruction in patients who had undergone CPM, our study is not able to evaluate this hypothesis.

Age and risk-reducing surgery

Women over the age of 65 years were the least likely to undergo CPM or reconstruction. While women over the age of 65 years made up 34% of the entire study population, only 15% of patients who underwent CPM were over the age of 65 years. Multiple medical comorbidities are a common reason for patients not to undergo surgery or reconstruction; however, only 4% of the entire study population had more than 1 comorbidity, of which 17% underwent CPM and 22.3% underwent reconstruction. Furthermore, post-menopausal women are more likely to have ER⁺/PR⁺ tumors (28). With endocrine therapy as a treatment option for patients with ER⁺/PR⁺ tumors and chemoprevention for the contralateral breast, providers may opt for endocrine therapy over surgery in patients over the age of 65 years due to concerns over ability to tolerate surgery or other more pressing health risks (29,30).

This study found that patients with ER⁻/PR⁻ tumors were most likely to undergo CPM but less likely to undergo reconstruction. A proportion of 14.5% of the total population had ER⁻/PR⁻ tumors; however, 36% of patients with ER⁻/PR⁻ tumors underwent CPM while only 30% of patients with ER⁺/PR⁺ tumors received such treatment. Given the increased frequency of ER⁻/PR⁻ tumors and the decreased percentage of CPM among Black women, our findings suggest that ER/PR status is unlikely to be confounding the differences in CPM usage among differing ethnicities. Furthermore, previous studies have shown marked variability in the ER/PR status of tumors among women of Asian ethnicities. Given that the lowest percentages of CPM were found within this patient population, ER/PR status is less likely to contribute to the decreased CPM observed in non-White women (31). However, ER/PR status may play a role in the decreased use of reconstruction among non-White women.

High-risk and genetic mutation status and CPM

A key indication for CPM is management of breast cancer in patients with *BRCA1/2* mutations or strong family history given the increased lifetime risk of developing breast cancer as well as increased likelihood of second contralateral or ipsilateral primary breast cancer (32,33). A limitation of our study is the lack of available information regarding genetic mutation status of patients or family history of breast and ovarian cancer. However, prior research reported that only 31% of women undergoing CPM have a strong family history of breast cancer or *BRCA1/2* mutation. This suggests that estimated high risk of developing contralateral breast cancer may not be driving this effect but perhaps perceived risk. Buchanan *et al.* [2016] found that 88% of women in their study population underwent CPM based on patient preference as opposed to physician recommendation with 29% admitting to having already decided to undergo CPM prior to the consultation with a surgeon (34). Furthermore, studies have shown that minorities as well as patients from lower socioeconomic status often experience inferior communication with physicians (35-37). This finding emphasizes the importance of shared decision making and strong patient-physician communication as these play integral roles in patients' access to therapies.

Limitations

This study has some limitations. Firstly, due to the retrospective nature of the study, selection bias is possible. Secondly, information on some factors that may affect the use of CPM or reconstruction, such as previously mentioned family history of breast cancer or known genetic mutations, were not available within the NCDB, and this may have resulted in unaddressed confounding. Also, race and ethnicity were self-reported without genetic or ancestry confirmation.

Conclusions

Women over the age of 65 years and non-White women have decreased access to CPM and breast reconstruction. Poor communication between patients and physicians and subsequently lack of shared decision making likely plays a big role. Standardization of CPM and breast reconstruction discussion by individual providers and healthcare systems for all patients should be considered to ensure that all patients understand the risks and benefits and have access to CPM and reconstruction. As physicians' education on topics of communication and unconscious bias increase, providers are slowly improving communication with patients. As such, access to CPM and reconstruction in underserved populations such as minorities and elderly has slowly begun to increase; however, much work is still yet to be done.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://gs.amegroups.com/article/view/10.21037/gs-22-759/rc

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The Ohio State University Office of Responsible Research Practices deemed this study IRB-exempt. Informed consent was not required due to the retrospective nature of this study.

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