Cardio-Oncology

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Incidence and risk factors of trastuzumab-induced cardiac dysfunction in a predominantly Hispanic South Texas population: a descriptive study

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Abstract

Background Trastuzumab, a monoclonal antibody against human epidermal growth factor receptor 2 (HER2), is often the first line treatment for HER2 positive breast cancer. Although trastuzumab is effective, it has cardiotoxic effects and therefore requires cardiotoxicity monitoring via serial transthoracic echocardiograms (TTEs). We aimed to evaluate risk factors for trastuzumab related cardiac dysfunction in a South Texas population that is uniquely a majority Hispanic population.

Methods A retrospective study was conducted of female patients with HER2-positive breast cancer who received trastuzumab treatment from 2015 to 2021. A total of 180 patients were identified. Patients without a baseline TTE and a baseline left ventricle ejection fraction (LVEF) less than 53% were excluded. The final sample size included 132 patients. Cardiac dysfunction was defined as a drop in LVEF by more than 10% to less than 53% during the 1-year study period.

Results The incidence of cardiac dysfunction was 6% in the study population. Hispanic/Latino patients composed 58% of the study population and represented 50% of patients who experienced cardiotoxicity. Of the patients who developed cardiotoxicity, 50% had hypertension, 25% had hyperlipidemia, 12.5% had type 2 diabetes mellitus, and 12.5% had previous coronary artery bypass grafts. A total of 12.5% had a history of radiation, 25% had a history of anthracycline therapy, 37.5% were former smokers, and 25% were former alcohol users.

Conclusions The incidence of trastuzumab-related cardiotoxicity in this Hispanic/Latino majority-minority population was 6%, which is surprisingly lower than the 9% cardiotoxicity rate observed in a predominantly white population in a previous study by Otchere et al., in 2023. Further studies are needed to determine the factors contributing to the reduced cardiotoxicity rate observed in this Hispanic population.

Keywords Trastuzumab, Cardiotoxicity, Cardio-oncology, Health disparities, Breast cancer

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Introduction

Breast cancer is the most frequently diagnosed cancer among women in the United States and accounts for up to 1 in 10 newly diagnosed cancers in women per year [1]. The human epidermal growth factor 2 (HER2) oncogene is overexpressed in approximately 20% of primary invasive breast cancers and is known to correlate with high mortality rates [2, 3]. Trastuzumab is a monoclonal antibody that works by inhibiting HER2 signaling pathways [2]. The current first-line treatments for HER2-positive breast cancer include trastuzumab monotherapy, with a taxane, or with an anthracycline. Treatment with trastuzumab has been shown to decrease both HER2-positive breast cancer mortality and recurrence [4].

Studies have also shown that cardiovascular mortality is greater in breast cancer patients than in the general population [5]. This knowledge calls for a better understanding of the effects of using chemotherapy agents with potential cardiotoxic effects in this population. Treatment with trastuzumab is associated with a low to moderate risk of cardiotoxicity, namely cardiac dysfunction [6]. The overall incidence of trastuzumab induced cardiac dysfunction has been reported to range between 8 and 35.6% in various studies [7, 8]. A meta-analysis examining clinical trials of patients receiving treatment with trastuzumab noted an increased risk for a reduction in LVEF and a higher incidence of severe heart failure in patients treated with trastuzumab compared to those without trastuzumab exposure [6]. A similar pooled analysis of current studies on trastuzumab induced cardiotoxicity revealed that 11.3% of patients receiving trastuzumab treatment experienced a cardiac event with the most common event noted to be a reduction in left ventricular systolic function [9].

Risk factors associated with a greater likelihood of developing cardiac dysfunction with trastuzumab treatment include age over 50 years, previous or concurrent anthracycline use, length of trastuzumab treatment, high body mass index (BMI), and pre-existing cardiac dysfunction with a lower LVEF at initiation of treatment or antihypertensive treatment [3, 8, 10, 11]. Race and ethnicity have also been explored as potential risk factors. One study noted that the incidence of significant LVEF decline or onset of heart failure in black women was nearly two times greater than that in white women. Other studies have also noted similar patterns of increased risk of cardiotoxicity see.

n in black patients [12, 13].

However, there is limited data on the incidence of trastuzumab-induced cardiac dysfunction in Hispanic patients. The South Texas population is unique in that the population is predominantly Hispanic and has a higher prevalence of cardiovascular-related comorbidities. We aim to evaluate the incidence and risk factors for trastuzumab-induced cardiac dysfunction in a South Texas population with a predominantly Hispanic population.

Methods

Study design

A retrospective study was conducted using electronic health records (EHR) at Mays Cancer Center, home to the University of Texas Health San Antonio MD Anderson Cancer Center. The EHR was queried to extract all patients with a diagnosis of HER2-positive breast cancer and exposure to trastuzumab treatment between 2015 and 2021.

Study participants and inclusion criteria

This study included all women aged 18 years or older diagnosed with HER–2 positive breast cancer who received trastuzumab treatment between 2015 and 2021. Patients without a baseline TTE and a baseline LVEF of less than 53% were excluded. A total of 180 patients were identified, 47 of these patients were excluded due to lack of a baseline TTE and 1 patient was excluded due to a baseline LVEF of less than 53%. The final sample size consisted of 132 patients (see Fig. 1). The inclusion and exclusion criteria for this study are detailed further in Fig. 2.

Covariate and outcome definitions

The variables extracted from the EHR included age, race, past medical conditions (hypertension, hyperlipidemia, type 2 diabetes mellitus, chronic kidney disease), social history (smoking, alcohol use), previous treatments (history of radiation, anthracycline exposure) and tumor receptor status. TTE data was also obtained to include TTEs done prior to treatment at 3 months, 6 months, 9 months, and 12 months. For each available TTE, the LVEF and global longitudinal strain (GLS) were recorded. For patients with missing follow-up data, the closest available TTE to the desired time was evaluated.

The study's outcome was cardiotoxicity, defined as a drop in LVEF by more than 10% to less than 53% during the 1-year study period.

Statistical analysis

We performed a bivariate analysis to examine the association of risk factors and socio-demographic characteristics with the incidence of cardiotoxicity. We used the chi-square test to describe the association between the incidence of cardiotoxicity and categorical/binary variables and t-tests for the association of the incidence of cardiotoxicity with continuous variables. All statistical analyses were conducted using R statistical software (version 4.2).

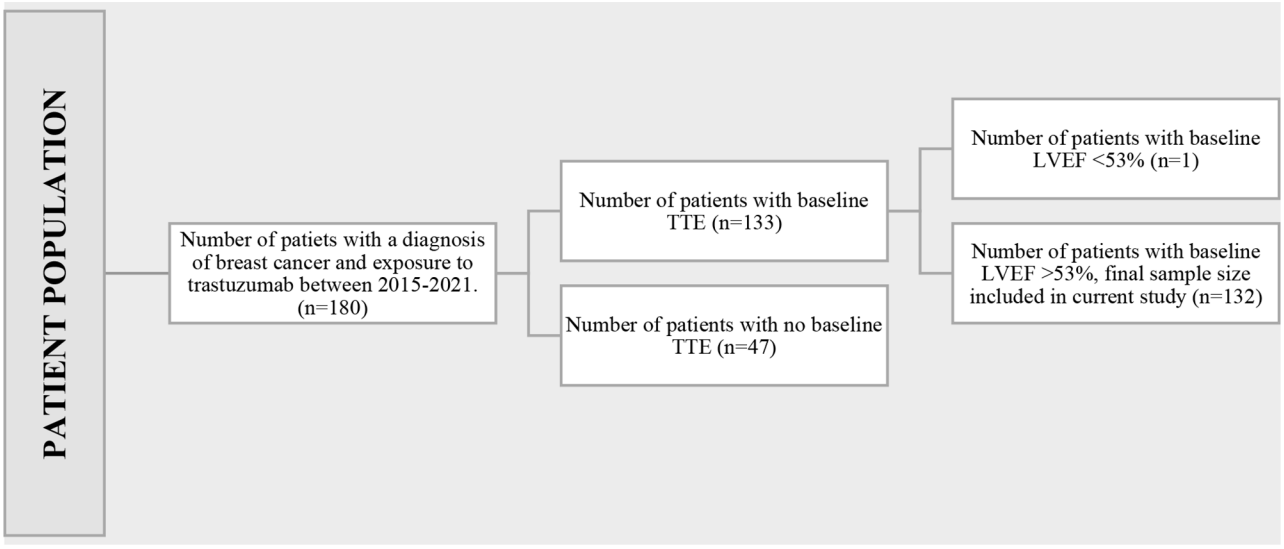

Fig. 1 Summary of study design and participants

Inclusion Criteria

- Female gender
- Age > 18
- Received 1st cycle of trastuzumab between the years 2015-2021
- Completion of trastuzumab treatment for at least 6 months before November 2022

Exclusion Criteria

- Males
- Known heart failure with baseline echocardiogram with LVEF <50%
- No baseline LVEF before chemotherapy initiation
- No follow-up echo/LVEF measurement within 6 months of initiation of trastuzumab therapy

Fig. 2 Detailed inclusion and exclusion criteria for this study

Ethical considerations

This research study was reviewed by the Institutional Review Board of the University of Texas Health Science Center San Antonio (Protocol # 23–038E) and was determined to be exempt on February 3rd, 2023. The study was approved for activation on February 6th, 2023.

Results

A total of 132 patients were included in the final analysis. The mean age at the time of diagnosis in the study population was 54.2 years. The average BMI of the study participants was 31. The mean baseline LVEF in this study population was 63%. The incidence of cardiotoxicity in this study population was 6% ($n = 8$ patients). The baseline characteristics of the study population are further outlined in Table 1.

TTE

Overall, the average number of echocardiograms received by patients was 3.54. Patients who developed cardiac dysfunction received an average of 4.62 echocardiograms during their trastuzumab treatment, whereas those without cardiotoxicity received an average of 3.47 echocardiograms.

Patients who experienced cardiac dysfunction.

Among those who developed cardiac dysfunction, 50% had hypertension (HTN), 25% had hyperlipidemia (HLD), 12.5% had type 2 diabetes mellitus (DM2), and 12.5% had previous coronary artery disease (CAD). In terms of cancer treatment, 12.5% of patients had a history of radiation, 25% had a history of anthracycline therapy, and 12.5% had their trastuzumab treatment ended prematurely. A total of 37.5% of patients in the cardiotoxicity population were former smokers and 25% were former alcohol users.

Table 1 Descriptive statistics of risk factors associated with cardiotoxicity present in our study population

Descriptive Risk Factors of Incidence of Cardiotoxicity within the overall population			
	Overall	**No**	**Yes**
n	132	124	8
Age at diagnosis (mean) (SD)	54.24 (13.02)	54.11 (13.12)	56.25 (12.12)
Premature Discontinuation of Trastuzumab (%)	17 (13)	16 (13)	1 (12.5)
Baseline LVEF (mean) (SD)	62.87 (4.56)	62.91 (4.60)	62.23 (4.16)
BMI (mean) (SD)	30.89 (7.81)	30.97 (7.70)	29.69 (9.77)
Hx of PCI (%)	2 (1.5)	2 (1.6)	0 (0.0)
Hx of CAD (%)	2 (1.5)	1 (0.8)	1 (12.5)
Hx of Radiation Therapy (%)	40 (30.8)	39 (32)	1 (12.5)
Hx of Anthracycline Therapy (%)	15 (11.6)	13 (10.7)	2 (25)
Positive ER receptor status (%)	83 (62.9)	79 (63.7)	4 (50.0)
Positive PR receptor status (%)	61 (46.2)	58 (46.8)	3 (37.5)
HTN (%)	67 (50.8)	63 (50.8)	4 (50.0)
HLD (%)	39 (30.5)	37 (30.8)	2 (25)
CKD (%)	9 (6.9)	9 (7.4)	0 (0.0)
DM2 (%)	29 (22.3)	28 (23)	1 (12.5)
Number of TTEs (mean) (SD)	3.54 (1.09)	3.47 (1.08)	4.62 (0.52)
Race			
Black/African American	9 (6.9)	8 (6.6)	1 (12.5)
Caucasian	115 (88.5)	108 (88.5)	7 (87.5)
Other	6 (4.6)	6 (4.9)	0 (0.0)
Hispanic/Latino Ethnicity (%)	77 (58.3)	73 (58.9)	4 (50)
Previous smoker (%)	31 (23.7)	28 (22.8)	3 (37.5)
Previous alcohol use (%)	41 (31.8)	39 (32.2)	2 (25)

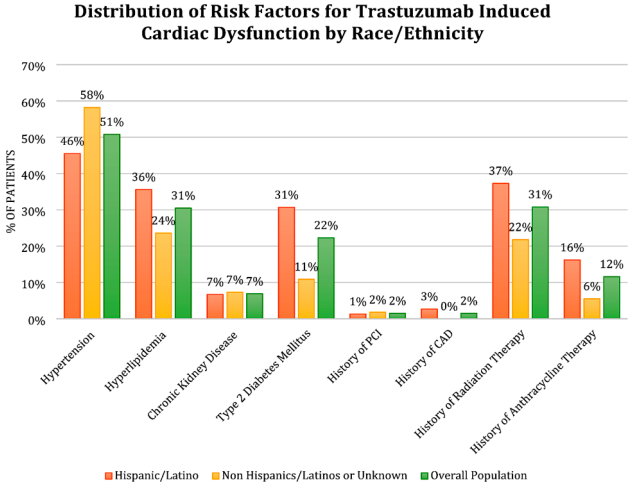

Fig. 3 Distribution of risk factors for trastuzumab-induced cardiotoxicity by race/ethnicity

Race/ethnicity

Within this study population, White/Caucasian individuals made up 88.5% of the population, African American individuals made up 6.9% of the population, and 4.6% of patients defined their ethnicity as other. Of the 115 White/Caucasian individuals included in this study population 58.3% self-identified as Hispanic/Latino. Of all the patients who experienced cardiotoxicity, 50% were Hispanic/Latino and 12.5% were African American.

Table 2 Racial and ethnic distribution of trastuzumab induced cardiotoxicity incidence rates

	Overall Population	**Development of Cardiotoxicity**	
		No	**Yes**
African American	9 (6.9%)	8 (6.6%)	1 (12.5%)
Caucasian/White	115 (88.5%)	108 (88.5%)	7 (87.5%)
Other	6 (4.6%)	6 (4.9%)	0 (0%)
Hispanic/Latino	77 (58.3%)	73 (58.9%)	4 (50%)

*Some patients identifying as Caucasian/White identified themselves as Hispanic/Latino. However, other patients who self-identified as Hispanic/Latino did not identify themselves as Caucasian/White

None of the patients identified as other races/ethnicities experienced cardiotoxicity. (see Table 1). The prevalence of HLD, DM2, and history of CAD was greater among the Hispanic/Latino individuals than that of the rest of the studied population. However, HTN, CKD, and history of CAD with stent placement were the only risk factors noted to be of lower or equal in prevalence in the Hispanic/Latino population compared to the rest of the studied population (see Fig. 3) (See Table 2).

Hispanic/latino patients

A total of 77 patients self-identified as Hispanic/Latino ethnicity. Within this population, 4 patients experienced cardiac dysfunction, translating to an incidence of cardiotoxicity of 4/77 (5.19%). The mean age of these patients was 54 years, and the average BMI was 31. The baseline

Table 3 Distribution of risk factors for trastuzumab-induced cardiotoxicity for patients of Hispanic/Latino ethnicity

Incidence of Cardiotoxicity based on Risk Factors for patients of Hispanic/Latino Ethnicity			
	Overall	**No**	**Yes**
n	77	73	4
Age at diagnosis (mean) (SD)	54.34 (13.99)	54.07 (14.19)	59.25 (9.36)
Baseline LVEF (mean) (SD)	63.00 (4.63)	63.05 (4.60)	62.00 (5.89)
BMI (mean (SD))	31.27 (7.91)	31.26 (7.82)	31.41 (10.75)
Premature Discontinuation of Trastuzumab (%)	11 (14.5)	10 (13.9)	1 (25.0)
Hx of PCI (%)	1 (1.3)	1 (1.4)	0 (0.0)
Hx of Radiation Therapy (%)	28 (37.3)	28 (39.4)	0 (0.0)
Hx of Anthracycline Therapy (%)	62 (83.8)	59 (84.3)	3 (75.0)
Hx of Anthracycline Therapy (%)	12 (16.2)	11 (15.7)	1 (25.0)
Positive ER receptor status (%)	48 (62.3)	47 (64.4)	1 (25.0)
Positive PR receptor status (%)	35 (45.5)	35 (47.9)	0 (0.0)
HTN (%)	35 (45.5)	33 (45.2)	2 (50.0)
HLD (%)	26 (35.6)	24 (34.8)	2 (50.0)
CKD (%)	5 (6.7)	5 (7.0)	0 (0.0)
DM2 (%)	23 (30.7)	22 (31.0)	1 (25.0)
Hx of CABG (%)	2 (2.7)	1 (1.4)	1 (25.0)
Number of TTEs (mean) (SD)	3.45 (1.07)	3.38 (1.05)	4.75 (0.50)
Previous smoker (%)	18 (23.7)	17 (23.6)	1 (25.0)
Previous alcohol use (%)	20 (27.0)	19 (27.1)	1 (25.0)

LVEF within this subpopulation was 63%. Among individuals within this ethnicity group, 46% had HTN, 36% had HLD, 31% had DM2, 7% had CKD, and 3% had previous CAD. In terms of previous cancer treatment, 37% of patients in the Hispanic/Latino population received radiation treatment and 16% received prior anthracycline treatment (Table 3). Within the Hispanic/Latino population as a whole, 14.5% of patients had their trastuzumab treatment ended prematurely.

Discusson

This study was conducted in a South Texas population, which is a uniquely Hispanic majority-minority population. The Hispanic population is an understudied population in comparison to the White/Caucasian population. This is true for studies on trastuzumab-induced cardiac dysfunction.

Our study was conducted to bridge the gap in knowledge regarding trastuzumab-induced cardiotoxicity in a majority Hispanic population in the USA. The findings of our study were surprising in that there was a lower rate of trastuzumab-induced cardiotoxicity as compared to a Caucasian majority population conducted by Otchere et al. in 2023 [14]. In this study, we found that 6% of our Hispanic majority-minority population developed cardiotoxicity, while the study by Otchere et al. in 2023 found that the Caucasian majority population had a 9% incidence rate of trastuzumab-induced cardiotoxicity.

Comorbidities such as DM2, obesity, and HTN have a greater prevalence in Hispanic population [15–17]. Therefore, the authors of this study expected the cardiotoxicity rate in this study to be higher than that seen in the average (e.g., predominantly White/Caucasian) population{, #90}. In fact, the South Texas population is known to have a higher rate of comorbidities compared to other populations, according to South Texas Health Status Review in 2013 that showed a higher prevalence or incidence of obesity and diabetes in South Texas compared to the rest of Texas and even the nation [18]. Previous studies examining trastuzumab induced cardiotoxicity have shown much lower rates of Hispanic patients represented in their study population [14, 19]. Additional studies with a larger sample will be needed to replicate this study to confirm this finding.

Clinical implications, study implications

The findings of this study may have significant implications for clinical practice. Current guidelines recommend TTE monitoring for cardiotoxicity every 3 months for all populations. A recently published study by DeRemer et al. noted that disparities exist within cardiotoxicity screening rates for anthracycline cardiotoxicity among different racial populations. The authors of that study noted that Hispanic patients were less likely to receive cardiac surveillance at 6 months than compared to other populations [20]. Understanding the factors that contribute to the cardiotoxicity rate can help guide patient-provider discussions and further understanding of cardiotoxicity risk before trastuzumab treatment is initiated.

Study limitations

While our study provides novel insights into this unique population, it is not without limitations. The retrospective nature of our analysis and reliance on existing medical records may have induced potential bias. The sample size of this study was also limited, and the findings may not fully capture the true incidence of cardiotoxicity in our current population. This dataset was also limited by the transition between EHRs that occurred at our institution in July 2020. Additionally, many patients appeared to have received fragmented care spanning across multiple hospital systems. Due to limited access to other EHR systems, it is possible that some patients included in this study received appropriate TTE follow-up at other institutions or developed cardiotoxicity at other institutions.

Additionally, the UT Health San Antonio cardio-oncology clinic opened in September 2021. Since then, this clinic has been focused on increasing awareness and providing education for patients and clinicians regarding cardiotoxicity. The presence of this cardio-oncology clinic may have created a difference in cardiotoxicity rates compared to populations that do not have access to a cardio-oncology care.

Suggestions for future research

Further studies are needed to investigate larger Hispanic majority-minority populations to better understand the potentially lower incidence of cardiotoxicity within our population. Additionally, exploring genetic and molecular markers specific to Hispanic populations could further enhance our understanding and improve our ability to identify patients at high risk for developing trastuzumab-induced cardiotoxicity.

Moreover, a more in-depth examination of socioeconomic factors such as insurance status, geographic location, income, and educational level may offer valuable insights into why some individuals receive appropriate surveillance TTEs more frequently than others. Understanding these socioeconomic factors may help identify disparities and underscore unmet needs for education or interventions within our communities.

Lastly, a case series examining patients who developed cardiotoxicity in this cohort may help identify other unknown predisposing factors correlated with trastuzumab-induced cardiotoxicity. Whereas, other future studies should explore the impact of establishing a cardio-oncology clinic in communities on the frequency of cardiotoxicity surveillance and the incidence of cardiotoxicity.

Conclusions

In this descriptive retrospective study, we observed a 6% incidence rate of trastuzumab-induced cardiotoxicity in the Hispanic majority-minority population. Further studies are needed to investigate this observed lower incidence rate and to elucidate the factors contributing to it, which would be particularly interesting given that Hispanic communities tend to face more socioeconomic barriers and comorbidities compared to White/Caucasian populations.

Abbreviations

BMI	Body mass index
CAD	Coronary artery disease
HER	Electronic health records
HER2	Human epidermal growth factor receptor 2
LVEF	Left ventricle ejection fraction
TTE	Transthoracic Echocardiogram
GLS	Global longitudinal strain
HTN	Hypertension
HLD	Hyperlipidemia
CKD	Chronic kidney disease
DM2	Type 2 diabetes mellitus

Author contributions

Aditi Sharma, Maria E. Fierro, Samuel Governor, Aishwarya Kothare, Stella Pak, Karen Liu, Zuha Alam, Prince Otchere wrote and revised the manuscript.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Consent to participate

The study was exempt from consent requirement due it being a quality improvement project.

Competing interests

The authors declare no competing interests.

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