

2018

Annual Report

Texas Tech Physicians Breast Care Center

NAPBC

National Accreditation Program for Breast Care Centers



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Texas Tech Physicians of El Paso Breast Care Center

This annual report details the clinical cancer activities Breast Care Center (BCC), Texas Tech University Health Sciences Center, for the year 2017.

A total of 177 breast primaries were evaluated and treated in both institutions during 2017. This information is from the last complete year as reported to the National Cancer Database.

We have implemented numerous strategies to improve breast cancer care and the quality of life and outcome of breast cancer patients in El Paso, TX. We have a Breast Care Program and work along with our affiliate University Medical Center to provide comprehensive breast care to those in our community including a lymphedema program through outpatient services.

Also, by improving patient's education and adherence to strict national guidelines, we have reduced rates of mastectomies and improved breast conserving surgeries in patients with early stage breast cancer. Disproportionately high rates of unnecessary mastectomies are common in underserved and non-affluent communities and among Hispanics nationwide.

By increasing awareness about the importance of cancer research, and the representation of Hispanics and dissipating myths and stigma about participating in clinical trials, we continue to actively enroll cancer patients in various local regional and national cancer clinical trials since 2012. A website has been created along with quarterly newsletters widely distributed in the community to promote cancer education and awareness, with a focus on breast cancer.

Our plan for The Texas Tech Physicians of El Paso Breast Care Center is to continue to strive for optimal cancer patient care. University Medical Center will strive to meet the standards set by the American College of Surgeons, National Accreditation Program for Breast Centers for continuance of our approved cancer program. The goal of patient therapy is to meet the National Comprehensive Cancer Network (NCCN) guidelines, while ensuring patients have the best quality of life possible.

Karinn Chambers, M.D, ACNP-BC
Breast Program Leadership

MEMBERS OF THE 2018 STEERING COMMITTEE

Karinn Chambers, MD,
Breast Program Leadership
Breast Surgery

Anoop Ayyappan, MD
Diagnostic Radiology

Lisa Gutierrez, MD
Diagnostic Radiologist

Victor Olivas, MD
Surgery

Sumit Gaur, MD
Medical Oncologist

Sandra Alderete, RN
Patient Navigator

Mary Licon, LMSW
Social Worker

Martha Armendariz, CTR
Certified Tumor Registrar

Melissa Valencia-Gonzalez, RHIT, CTR
Certified Tumor Registrar

Alonso Andrade, MD
Surgery

Roberto Gamez, MD
Pathology

Anuradha Gupta, MD
Radiation Oncology

Alexander Philipovski, MD
Medical Oncology

Rosalinda Heydarian, Hem/Onc, NP
Genetics Professional/Counselor

Aleli Campbell
Research Coordinator

Alison Kennedy, RN
UMC Patient Navigator

Dianne Ramirez, RHIT, CTR
Certified Tumor Registrar

CANCER RELATED CONFERENCES

Staff physicians, resident physicians, and allied health professionals who work closely with hospital clinicians and patients attend the Breast Cancer Conferences. The Breast Cancer Conference meets bi-monthly. Attendees include Medical Oncology, Surgery, Radiology, Pathology, Internal Medicine and Radiation Oncology.

During 2018, there were 21 Breast Cancer Conferences held with a total of 192 patients being presented. During the 2018 Tumor Conferences, 100% of cases were prospective case presentations. Multidisciplinary attendance by department for tumor conference shows an average attendance by Medical Oncology at 100%, Radiation Oncology at 100%, Surgery 100%, Radiology at 100%, Pathology 100% and Allied Health at 100%. Presentations at Cancer Conferences include history and physical findings, surgical findings, staging and review of radiology and pathology studies, type of treatment received, and review of pertinent medical literature. Treatment recommendations are discussed. The majority of cancer cases are presented at Cancer Conferences. Topics of discussion typically focus on treatment guidelines for similar cases that may occur at some future date.

CANCER REGISTRY ACTIVITY REPORT

The Texas Tech Physicians of El Paso Breast Care Center was the first accredited NAPBC Breast Center in the region.

As an active part of the cancer team, the Cancer Registry at University Medical Center of El Paso collects, prepares, and presents data for conferences, committee meetings and studies. The registry's network of sources and the ability to collect comprehensive data and information assists in the daily practice and refining of special studies. The Registry has continued to offer these and other services since 1975. The Registry is responsible for the collection, maintenance, and analysis of this data.

The University Medical Center of El Paso Registry is currently maintaining the 80% follow up rate for all eligible analytic cases from the cancer registry reference date and is maintaining a 90% follow up rate for all eligible analytic patients diagnosed within the last five years meeting the 90% required by the Commission on Cancer.

The goal of the Cancer Registry is to provide the medical staff with data that will enable them to see the end results of their diagnosis and therapeutic efforts. The data is also sent to National Cancer Data Base and the Texas Cancer Registry.

A major objective of the cancer registry is to produce accurate and useful data. Well-documented quality control is essential if this objective is to be met and is required for approval status. To ensure accuracy and consistency, a 10% random physician review of cases is completed annually, and this includes review of class of case, primary site, histology, stage of disease, and first course treatment and College of American Pathologists (CAP) Protocols.

ONCOLOGY SUPPORT SERVICES

STAFF EDUCATION:

Orientation of registered nurses (RNs) with primary responsibility for oncology patients includes attendance of a two day Chemotherapy Competency Course, forty hours of one-to-one training at the Oncology Infusion Center, and review and development of relevant oncology policies and procedures. All registered nurses working with oncology patients are also evaluated utilizing an oncology competency-based program.

RN's are encouraged to obtain certification by taking the Oncology Nursing Society Certification exam given by the Oncology Nursing Certification Corporation. University Medical Center of El Paso presently has three Oncology Certified nurses (OCN).

ONCOLOGY NURSING SERVICES:

The Medical Unit provides in-patient services to those patients who require hospitalization. This can include symptom management, treatment of infections, pain control or complications associated with their treatment. There are seven dedicated beds for In-patient Oncology patients, three of which are private rooms. The Medical Unit also provides services for the Infusion Center after hours and on the weekend to ensure continuity of care. The nurses are qualified to administer chemotherapy and educate the patients regarding the necessary precautions and the associated side effects. The Medical Unit maintains education materials for patients and staff to include topics dealing with specific cancers, chemotherapy, nutrition, treatment modalities, venous access devices, and other issues related to cancer in both Spanish and English.

INFUSION CENTER SERVICES:

The Oncology Infusion Center is a beautiful state of the art facility with 16 infusion bays. Under the direction of Dr. Javier Corral, and two additional full time Oncologists, the staff at the Infusion Center administered outpatient services to 7095 patient visits in 2018. The Infusion Center is also supported by a full time Social Worker who assists patients with their financial needs as well as available community resources. Social Work staff is assigned to both the in-patient as well as the outpatient setting. The social worker has been instrumental in obtaining grant money to assist with the individual needs of the patients who are in need of additional support. A full range of services is provided to include chemotherapy, preventive IV therapy, Care of the Central Lines, comprehensive patient education, and necessary clinical procedures. In addition, University Medical Center is a member of the Cancer Care Network.

GENETIC COUNSELING:

Genetic risk assessment is provided to breast cancer patients seen at Texas Tech Breast Care Center that meet criteria for testing as per NCCN (National Comprehensive Cancer Network) guidelines. The patients are referred by the oncologists to the nurse practitioner who participated in Intensive Course of Genetic Risk Assessment through the City of Hope in Duarte, CA. Most of the patients

meet criteria for testing. Following a formal genetic assessment, the patients are tested. Results are provided to the patients by the NP or the oncologist when the patient is seen at time of follow up. Recommendations for each patient are made by the oncologist at the time of follow up.

CLINICAL TRIALS

University Medical Center, in collaboration with Texas Tech University Health Sciences Center, conducts clinical trial and clinical research activities to ensure that patient care approaches the highest possible level of quality.

Participation in cancer-related clinical research demonstrates that an independent peer-review mechanism consistent with national standards is in place and used. Research projects involving participation with human subjects must be approved by an internal or external institutional review board (IRB). Patients that participate in clinical trials provide informed written consent.

Patients eligible for clinical trials and clinical research activities are seen at our program for:

- Diagnosis and/or treatment and placed in a cancer-related clinical trial through the program;
- Diagnosis and/or treatment and placed in a cancer-related clinical trial through the office of a staff physician;
- Diagnosis and/or treatment and placed in cancer-related clinical trial through another program (referral); or
- Any reason and placed in a cancer prevention or cancer control clinical trial.

A data manager/clinical research professional is available at University Medical Center and at Texas Tech University HSC to assist with enrolling patients, ensuring that patients meet eligibility criteria, monitoring patient accrual, and identifying and providing information and education about new cancer-related clinical trials. Patient accrual is monitored and reported to the cancer committee by the clinical research representative. In 2018, a total of 218 breast cancer patients were enrolled in clinical trials.

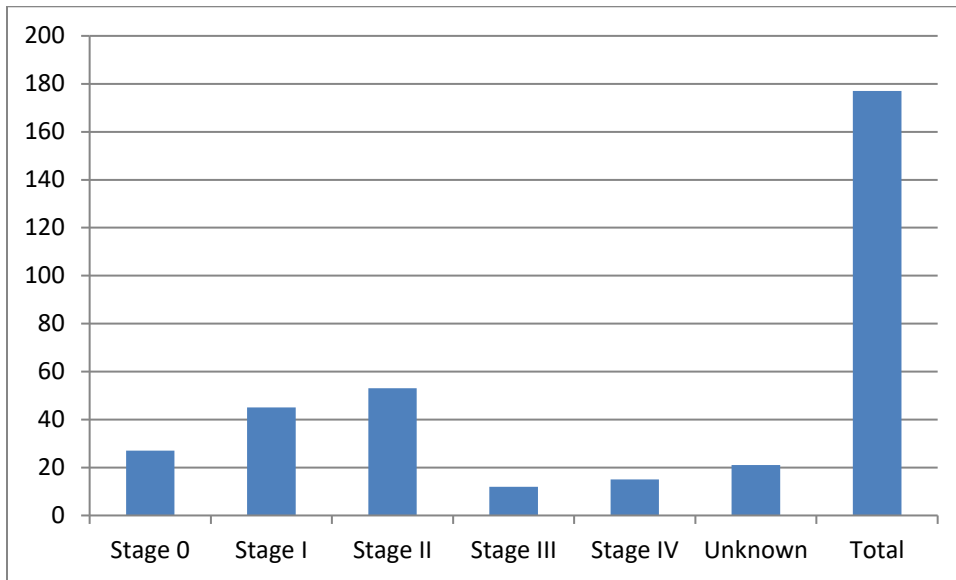
2018 Cancer Related Clinical Trials Approved for Conduct at University Medical Center of El Paso

Name of Clinical Research Trial	Sponsor	IRB Approval #	Principal Investigator	Patients Enrolled in 2018
A phase III, randomized clinical trial of standard adjuvant endocrine therapy +/- chemotherapy in patients with 1-3 positive nodes, hormone receptor-positive and HER-2 negative breast cancer with recurrence score (RS) of 25 or less (S 1007 El Paso)	Southwest Oncology Group (SWOG)	E13068	Alexander Philipovskiy, M.D.	6
Phase III trial of continuous schedule AC + G vs. Q2 week schedule AC, followed by Paclitaxel given either every 2 weeks or weekly for 12 weeks as post-operative adjuvant therapy in node positive or high-risk node negative breast cancer (S0221)	SWOG/Amgen	E13086	Alexander Philipovskiy, M.D.	3
A randomized multicenter pivotal study of CDX-011 (CR011-vcMMAE) in patients with metastatic CPNMB over-expressing, triple-negative breast cancer (The METRIC study)	CellDex	E141181	Alexander Philipovskiy, M.D.	5
A randomized phase III trial of endocrine therapy plus Entinostat/placebo in patients with hormone receptor-positive advanced breast cancer (E2112)	ECOG	E16033	Alexander Philipovskiy, M.D.	4
ALternate approaches for clinical stage II or III Estrogen Receptor positive breast cancer NeoAdjuvant TrEatment (ALTERNATE) in postmenopausal women: A phase III study (A011106)	NCI	E16128	Alexander Philipovskiy, M.D.	1
Prevalence of genetic mutations in Hispanic/Latina women diagnosed with breast cancer.	Investigator Initiated	E18059	Alexander Philipovskiy, M.D.	77
Adherence of Hispanic / Latina Breast Cancer - Patients to Adjuvant Aromatase Inhibitors - (AIs) Phase II	Investigator Initiated	E17086	Alexander Philipovskiy, M.D.	2
			Total	98

Retrospective				
Echocardiographic changes during adjuvant therapy in Hispanic women with HER-2 neu expressing breast cancer (sg-6)	PHI Only	E17080	Sumit Gaur, MD	120
			Total	218

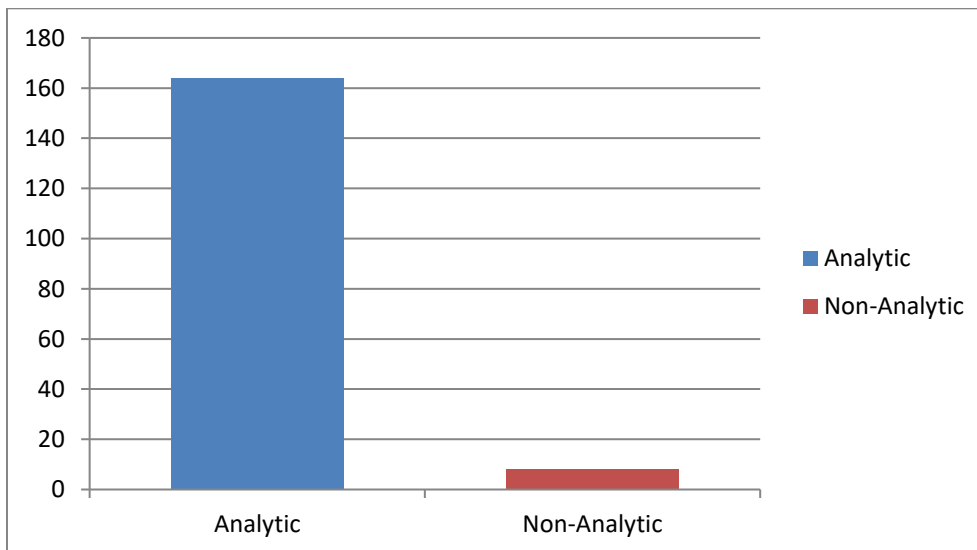
Statistical Review 2017 Data

Stage at Diagnosis



Stage 0	Stage I	Stage II	Stage III	Stage IV	Unknown	Total
27	45	53	16	15	21	177

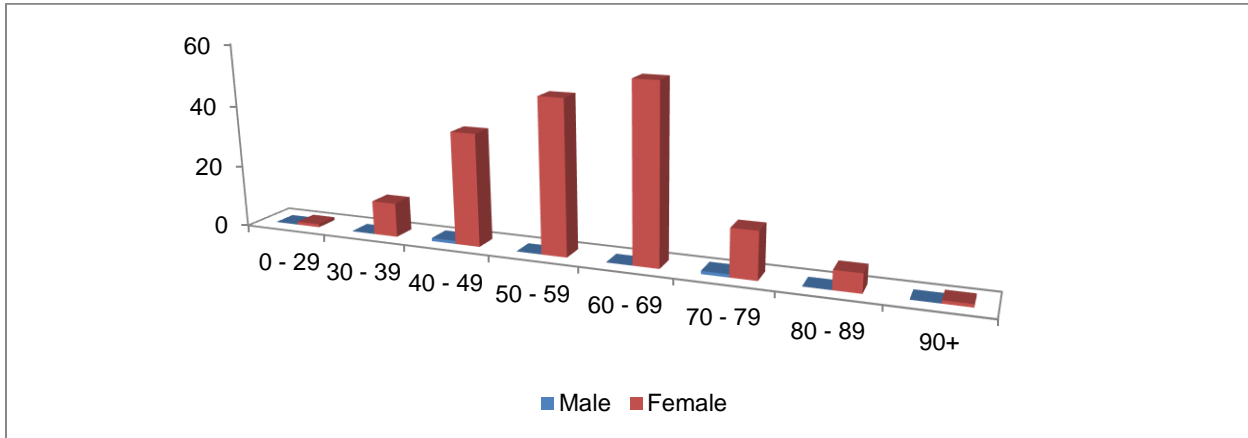
Total Breast Cancer Caseload 2017



Analytic	Non-Analytic	Total
151	26	177

Age at Initial Diagnosis

2017 Data



Age	Male	Female	Total
0-29	0	1	1
30-39	0	11	11
40-49	1	36	37
50-59	0	49	49
60-69	0	56	56
70-79	1	15	16
80-89	0	6	6
90+	0	1	1
Total	2	175	177

Adherence to aromatase inhibitors(AI's) in Hispanic patients with early stage breast cancer.

Alexander Philipovski, Aleli Campbell, Rosalinda Heydarian, Krystal Lin, Zeina A. Nahleh

Background: Adherence to Aromatase Inhibitors (AIs) is essential for the effective prevention of breast cancer recurrence. We sought to evaluate adherence to AIs as well as possible factors behind non-adherence in a large American-Mexican border city with predominantly Hispanic population.

Methods: After IRB approval, women with Stages I-III breast cancer treated at the Texas Tech breast care center in El Paso, TX were included if they were receiving adjuvant AI therapy. We utilized the validated Morisky Medication Adherence Scale (MMAS-8) to determine AI compliance. In addition, a question to indicate reasons for noncompliance was added.

Results: 87 patients were enrolled, median age was 61 years; 78 (90%) were identified as Hispanic. The majority of participants were women of low socioeconomic status 53 (61%) with an annual income of < \$15,000. MMAS-8 results showed 35 (40%) patients admitted to forgetting to take their AI pill. Additionally, 71 (82%) of the patients denied forgetting to take the AI pill within the past two weeks. 11 (13%) patients admitted to sometimes having difficulty remembering to take their AI medication, and 74 (85%) stated never or rarely having difficulty remembering to take their AI medication. 50 (57.5%) patients provided a reason why they did not take their AI pill, 35 (40%) cited forgetfulness, 14 (17%) cited other reasons including cost, limited insurance coverage, lack of transportation involved in obtaining the medication and timely prescription refills, and only 1(1%) due to side effects.

Conclusions: Non-adherence to AI appears to be prevalent among Hispanic patients with breast cancer. Main causes of noncompliance are forgetfulness and financial reasons. Healthcare providers could reinforce educating patients about the importance of compliance. Financial assistance may also be helpful in improving AI compliance. Clinical trial information: NCT03144037.

Left Ventricular Ejection Fraction (LVEF) changes during HER-2 directed therapy in a predominantly Hispanic population with a high prevalence of cardiovascular risk factors

S. Gaur, MD, M. McAlice, DO, A. Alshaban, MD, A Mahfoud, MD, J. Corral, MD, A. Philipovskiy

Abstract: Trastuzumab based therapy is recommended for patients with early stage HER-2 overexpressing breast cancer, because it improves survival. Significant racial disparities exist in the receipt of trastuzumab with minorities being 25% less likely than whites in being treated with it. (Reeder-Hayes K et al, JCO 2016; 34:2003-2009). Trastuzumab can affect cardiac function. Cardiac complications associated with trastuzumab are influenced by age and pre-existing risk factors including obesity, hypertension, dyslipidemia and glucose intolerance. These co-morbidities occur more frequently in medically underserved minority populations and may influence the practitioner's decision to use trastuzumab. We previously identified a high prevalence of metabolic syndrome and obesity in our predominantly Hispanic, medically underserved patient population (SABCC 2015 abstract P1-09-07). For this study, we analyzed the echocardiographic stat and cardiac complications associated with trastuzumab based chemo-immunotherapy in this patient population.

Methods: All patients diagnosed with early stage (stage 1, 2, or 3) HER2 positive breast cancer between Jan 1st 2010 and Jan 1st 2015 at our institution, were identified. Age, race, body mass index, pre-existing cardiovascular risk factors (diabetes mellitus, hypertension, dyslipidemia) antihypertensive medication use was collected. Tumor size, nodal status, ER, PR, and HER 2 status were recorded. Chemotherapy regime used with trastuzumab was identified. All echocardiograms obtained were reviewed for ejection fraction changes. Repeated measures one sided ANOVA was used to analyze changes in EF. Hospitalization for cardiac complications was recorded. Early interruption of planned therapy and its reason were recorded. Study was approved by the institutional IRB.

Results: A total of 60 patient were treated with trastuzumab based on chemo-immunotherapy over the study period. 93% were Hispanic, median age was 61 years (Range 31-88), 40% had hypertension, 35% had dyslipidemia, 35% had glucose intolerance or type II diabetes mellitus and 70% were overweight or obese. 33% were dependent on Medicaid or other charity care. 26% has stage 1, 37% has stage 2, and 37% has stage 3 cancer. Docetaxel, carboplatin, trastuzumab (TCH) was the most commonly used regimen (63%) followed by doxorubicin, cyclophosphamide, paclitaxel, and trastuzumab (28%). Ten patients (16.6%) required early discontinuation of cytotoxic chemotherapy. Only 1 patient was unable to complete planned 1 year of trastuzumab due to the declining ejection fraction. There were no hospitalizations related to cardiac events during therapy. Trastuzumab based treatment elicited statistically significant changes in LVEF over time, $F(2,98)=13.974$, $p<.0005$, with LVEF decreasing from $65.4\pm.844$ prior to therapy to $64.7\pm.724$ during 3-6 months of therapy and $62.2\pm.81$ at the end of therapy. Two patients had a decline on $LVEF\geq 10\%$ of these, 1 resolved at follow up ECHO in 6 weeks.

Conclusion: In a predominantly Hispanic, HER 2+ breast cancer cohort, with a high prevalence of cardiovascular risk factors and limited health care access, we found that the vast majority were able to complete 1 year of trastuzumab without significant cardiac complications. As trastuzumab improves survival, practitioners should adhere to national guidelines regarding trastuzumab use as much as possible.

GLOSSARY OF TERMS

Class of Case	A determination of the patient's diagnostic and treatment status at first admission to University Medical Center of El Paso.
Analytic	Cases which were first diagnosed and/ or received all or part of their first course of treatment at UMC.
Non-Analytic	Cases diagnosed and received entire first course of treatment prior to admission to UMC, cases diagnosed at autopsy.
First Course	The initial course of tumor-directed treatment, or series of treatments, usually initiated within the first four months after diagnosis.
AJCC	American Joint Committee on Cancer
ACoS	American College of Surgeons
NAPBC	National Accreditation Program for Breast Centers
NCDB	National Comprehensive Cancer Network
CoC	Commission on Cancer
CAP	College of Pathologists