

Bringing the Fight to Cancer.

2016 Annual Report



Quality Study

Adherence to Adjuvant Systemic Therapy Following Primary Surgery in Stage II Breast Cancer Patients: Baylor Scott & White Medical Center – McKinney 2012-2014

Data Reviewed by Lynn Canavan, MD, Chairman Cancer Committee

Introduction

The American Cancer Society estimates that approximately one in eight women in the United States will develop invasive breast cancer during their lifetime with about 246,000 new cases of invasive breast cancer being diagnosed in 2016¹. In addition to high incidence rates, breast cancer is the second leading cause of cancer death in women. Death rates from breast cancer have decreased since 1989 resulting in more than 2.8 million breast cancer survivors in the United States². Improvements in survival rates are attributed to advances in detection and treatment³⁻⁵.

Early stage breast cancer (stages I or II) is the most common invasive breast cancer in the United States. Stage II breast cancers are larger than stage I cancers and/or have spread to nearby lymph nodes. Stage II is divided into two categories: stage IIA and stage IIB. The difference is determined by the size of the tumor and whether the cancer has spread to lymph nodes. Women

diagnosed with early stage breast cancer live at least five years beyond diagnosis. Survival rates for stage IIA may be slightly higher than for stage IIB. However, all women with stage II breast cancer are considered to have a good prognosis⁶.

Treatment for early stage breast cancer usually involves a combination of surgery, radiation therapy, chemotherapy or hormone therapy. Primary surgery (lumpectomy or mastectomy) is typically the first step in treating early stage breast cancer. The need for and selection of various local and systemic therapies are based on several prognostic and predictive factors. Factors such as ER, PR and HER2 help predict response to therapy. ER and PR tumor status should be determined for all samples of invasive breast cancer⁷. In addition to ER and PR, the determination of HER2 tumor status is recommended for all newly diagnosed invasive breast cancers. After surgery, adjuvant systemic therapy in the form of chemotherapy, radiation or hormone therapy should be considered based on individual risk and predicted sensitivity to treatment. The decision to use systemic adjuvant therapy

requires collaboration between the health care team and patient in determining the balance between risk of recurrence and the benefits from therapy.

Several published results from the Early Breast Cancer Trialists Collaborative Group (EBCTCG) demonstrate the benefit of adjuvant systemic therapy in reducing cancer recurrence following primary surgery. In a meta-analysis, results show that adjuvant chemotherapy and tamoxifen demonstrated strong reductions in the odds of cancer recurrence and death in all age groups for chemotherapy and endocrine therapy^{8,9}. In addition, a meta-analysis by the EBCTCG demonstrated a reduction in 10-year risk of recurrence in those who received whole breast irradiation versus those who did not following lumpectomy¹⁰. The results of EBCTCH meta-analysis¹¹ showed that radiation therapy and axillary node dissection following mastectomy reduced both recurrence and breast cancer mortality in women with one to three positive lymph nodes. Lastly, patients with invasive breast cancers that are hormone receptor positive should

be considered for adjuvant endocrine therapy regardless of patient age, lymph node status, or whether chemotherapy is to be administered¹².

The purpose of the following analysis is to evaluate treatment patterns based on hormone receptor status (ER/PR) and HER2 amplification following primary surgery in stage II breast cancer patients treated at Baylor Scott & White Medical Center - McKinney from 2012-2014.

Methods

Using the Baylor Scott & White Health North Texas Cancer Registry data, all breast cancer cases stage II receiving primary surgery at Baylor Scott & White – McKinney from 2012-2014 were compared to the evaluation and treatment guidelines published by the NCCN. Stage II patients were identified using the Pathology AJCC stage code and filtered by histology codes (85003, 85203, 85223). Using the cancer directed surgery code provided by the cancer registry, surgery type was grouped into lumpectomies and mastectomies. The report provides demographic data for primary surgery types at the facility and a breakdown of primary surgery type by AJCC stage code. In addition to descriptive data, the following 2016 NCCN guidelines act as the framework for the analysis:

1. Following lumpectomy, radiation therapy to follow chemotherapy when chemotherapy is indicated.
2. Following mastectomy, radiation therapy recommended.

3. ER Positive and/or PR Positive and HER2 Positive, adjuvant chemotherapy followed by endocrine therapy recommended.

4. ER Negative and PR Negative and HER2 Positive or HER2 Negative, adjuvant chemotherapy recommended.

Results

Breast Cancer Surgery

During the calendar years of 2012, 2013 and 2014, Baylor Scott & White – McKinney encountered 41 primary surgeries of which 20 were lumpectomies and 21 were mastectomies. In those patients receiving primary surgery, 68.29 percent were 51 years of age or above and 87.8 percent were white. Divided by AJCC stage treated at Baylor Scott & White – McKinney, 53.65 percent were IIA, 43.9 percent were IIB and 2.44 percent were II.

Treatment following Primary Surgery

Of those receiving a lumpectomy:

- 16 (80 percent) were ER Positive and/or PR Negative tumors.
- Four (20 percent) were ER Negative and PR Negative tumors.

All ER/PR Negative lumpectomy patients received surgery, chemotherapy and radiation. Lumpectomy patients ER Positive and PR Positive or Negative received adjuvant systemic therapy with the majority receiving radiation and chemotherapy.

Of those receiving mastectomies:

- 18 (85.71 percent) were ER Positive and PR Positive or Negative tumors.
- Three (14.28 percent) were ER Negative and PR Negative tumors.

The majority of mastectomy patients with ER Positive and PR Positive or Negative status received adjuvant chemotherapy and/or hormone therapy. Mastectomy patients with ER Negative and/or PR Negative status received either surgery only or surgery followed by chemotherapy.

According to the NCCN guidelines, radiation therapy is recommended following lumpectomy. Fifteen of the 20 patients receiving a lumpectomy at Baylor Scott & White – McKinney received radiation following surgery. Of the five without documentation of receiving radiation therapy, two patients were greater than 71 years of age. In addition, 80 percent of lumpectomy patients received chemotherapy. The guidelines also strongly recommend that mastectomy patients receive radiation therapy following surgery. A total of 23.8 percent of the mastectomy patients at Baylor Scott & White – McKinney received radiation therapy following surgery. This finding may be due to the nature of the tumor or radiation therapy was given prior to surgery in addition to the lack of treatment information documented in the Cancer Registry for the years of 2012-2014.

ER Positive and PR Positive or Negative Status with HER2 Positive Expression

Of all stage II breast cancer patients treated at Baylor Scott & White – McKinney, six patients presented with ER Positive and PR Positive or Negative Status with HER2 Positive expression. Three patients received a lumpectomy and three received mastectomy. The lumpectomy patients received radiation and chemotherapy in addition to surgery while the mastectomy patients received chemotherapy in addition to surgery. The NCCN guidelines recommend that patients with ER Positive and PR Positive or Negative tumors with HER2 Positive expression receive adjuvant chemotherapy followed by endocrine therapy. All patients received chemotherapy with three documented as receiving endocrine therapy.

ER Negative and PR Negative Status with Positive or Negative HER2 Expression

Of all stage II breast cancer patients treated at Baylor Scott & White – McKinney, seven patients presented with ER Negative and PR Negative tumor status with Positive or Negative HER2 expression. Four patients received a lumpectomy and three patients received a mastectomy. All lumpectomy patients received radiation and chemotherapy in addition to their surgery. Two of the three mastectomy patients received chemotherapy in addition to surgery with the third being 75 years of age and chemotherapy was not recommended. Given that hormone receptor status was negative for all patients, none received hormone therapy. According to NCCN guidelines, patients with ER Negative and PR Negative tumors and HER2 Positive or HER2 Negative expressions, adjuvant chemotherapy is recommended. Five of six

patients treated at Baylor Scott & White – McKinney received chemotherapy. The one outlier was 75 years old and was not felt to be able to tolerate chemotherapy due to medical comorbidities.

Discussion

The first course of treatment for stage II breast cancer is primary surgery either lumpectomy or mastectomy. Women treated with lumpectomy are treated with radiation therapy following surgery while women who have a mastectomy are typically treated with radiation if the cancer spreads to the lymph nodes. Systemic adjuvant therapy is recommended for women with stage II breast cancer. Systemic treatment can occur before or after surgery takes place. In some cases, systemic therapy will be started before surgery and continue following surgery.

Several studies published by the EBCTCG provide the framework for determining the decision to use systemic adjuvant therapy after surgical treatment. The decision to use systemic adjuvant therapy requires the consideration of various factors including the risk for disease recurrence and the benefit from applying adjuvant therapy. Importantly, the decision making process requires the collaboration between the health care team and the patient.

This analysis demonstrates that Baylor Scott & White – McKinney is in accordance with the examined NCCN guidelines for treatment following primary surgery in stage II breast cancer patients. A few cases did not meet recommended guidelines but this is likely due to the nature of the tumor and/or patient educated treatment decision.

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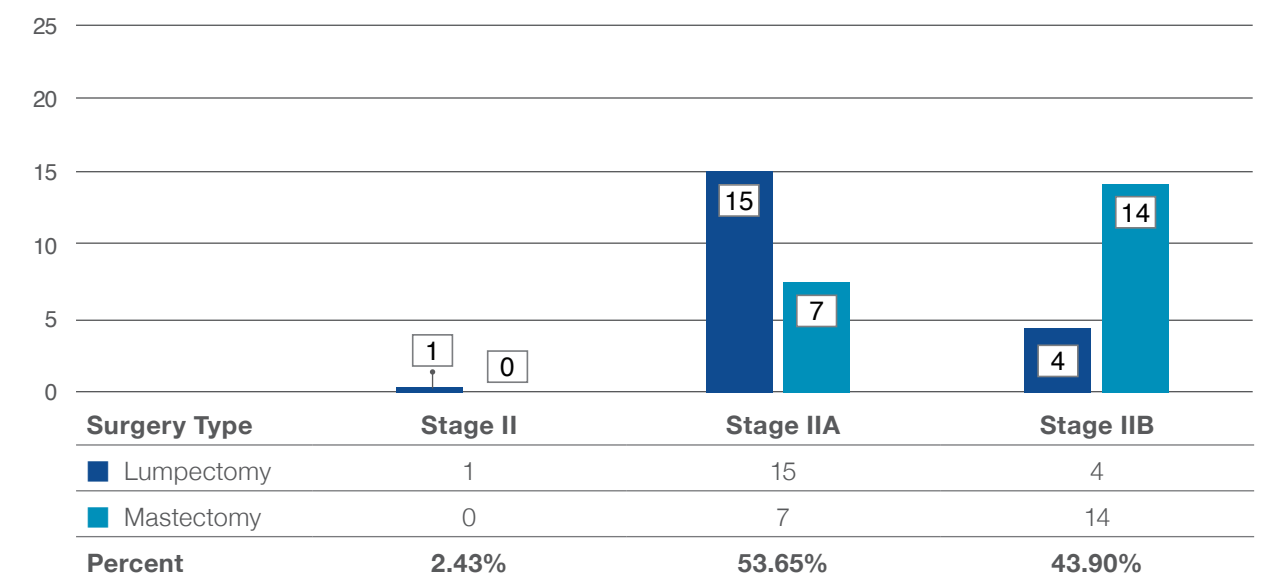
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Surgery Type	Total
Lumpectomy	20
Mastectomy	21
Total	41

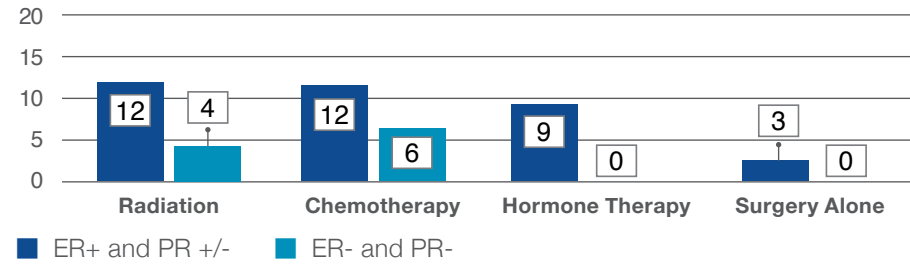
Age Group	Frequency	Percent
<40	5	12.19%
41-50	8	19.52%
51-60	10	24.39%
61-70	9	21.95%
71 or greater	9	21.95%
Total	42	100.00%

Race	Frequency	Percent
White	36	87.80%
Black	3	7.32%
American Indian or Alaska Native	1	2.44%
Unknown	1	2.44%
Total	41	100.00%

Breast Cancer Surgery Type by AJCC Stage
Baylor Scott & White Medical Center – McKinney 2012-2014

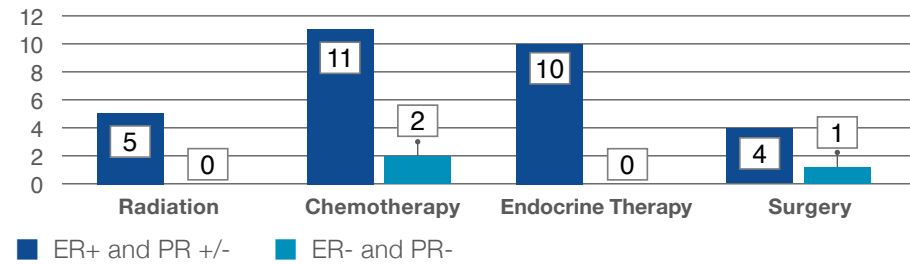


Treatment Type Following Lumpectomy Based ER/PR Status
Baylor Scott & White Medical Center – McKinney 2012-2014



Status	Lumpectomy Pts	Percent
ER + and PR +/-	16	80.00%
ER – and PR -	4	20.00%
Total	20	100.00%

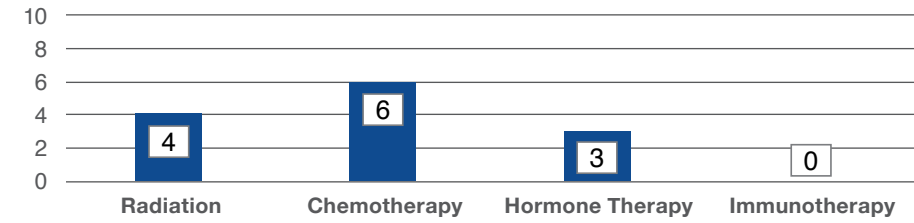
Treatment Type Following Mastectomy Based on ER/PR Status
Baylor Scott & White Medical Center – McKinney 2012-2014



Status	Lumpectomy Pts	Percent
ER + and PR +/-	18	85.71%
ER – and PR -	3	14.29%
Total	21	100.00%

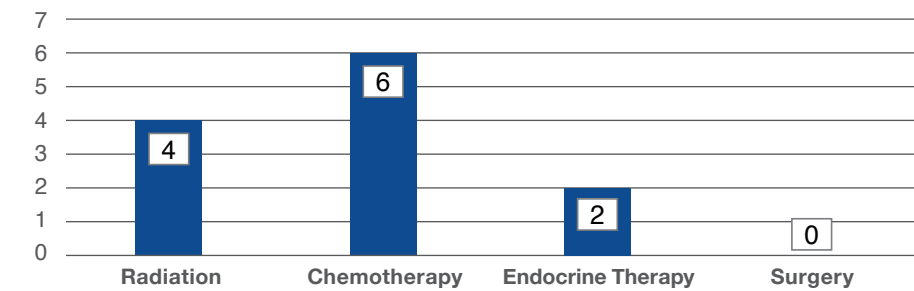
	Lumpectomy	Mastectomy	Total
ER+ and PR +/- and HER2 +	0	3	3
ER- and PR- and HER2 +/-	0	3	3
Total	0	6	6

Frequency of Treatment Based on ER+ and PR+/- and HER2+
Baylor Scott & White Medical Center – McKinney 2012-2014



ER+ and PR + or - and HER2 +	Lumpectomy	Mastectomy	Total
Surgery Only	0	0	0
Radiation/Chemo	1	0	1
Radiation/Chemo/Endocrine	2	1	3
Chemo	0	2	2
Total	3	3	6

Frequency of Treatment Based on ER- and PR- and HER2+/-
Baylor Scott & White Medical Center – McKinney 2012-2014



ER- and PR- and HER2 +/-	Lumpectomy	Mastectomy	Total
Radiation/Chemo/Immunotherapy	2	0	2
Radiation/Chemo	2	0	2
Chemo	0	2	2
Total	4	2	6



Cancer Screenings

Baylor Scott & White Medical Center – McKinney 2016

SCREENING TYPE	NUMBER OF 2016 SCREENINGS	NUMBER AT RISK	CANCER DIAGNOSIS OR ABNORMALITY
Breast	4,077	467	14
Colon	1,533	81	24
Low-Dose CT Lung	19	6	0

Cancer Registry

	NCDB Target	CoC State of Texas Performance Rate	CoC Census Region (West) Performance Rate	All CoC Programs Performance Rate	Baylor Scott & White – McKinney Performance Rate		
					2015 Forward	Diagnosis Year 2014 (CoC)	2013* 2014* 2015**
Breast Cancer							
BCS: Breast conservation surgery rate for women with AJCC clinical stage 0, I, or II breast cancer	NA	54.0%	57.0%	64.0%	NA	NA	64.0%
NbX: Image or palpation-guided needle biopsy (core or FNA) is performed for the treatment of breast cancer (Quality Improvement Measure - Released Spring 2014)	80.0%	88.8%	87.5%	87.3%	NA	NA	82.0%
HT: Adjuvant hormonal therapy: Tamoxifen or third generation aromatase inhibitor is considered or administered within 1 year (365 days) of diagnosis for women with AJCC T1cNoMo, or Stage II or III hormone receptor positive breast cancer (Accountability Measure - Released Fall 2008)	90.0%	90.5%	90.4%	93.2%	NA	NA	93.0%
MASRT: Radiation therapy is considered or administered following any mastectomy within 1 year (365 days) of diagnosis for women with >= 4 positive lymph nodes (Accountability Measure)	90.0%	82.0%	83.3%	87.8%	NA	NA	100.0%
BCRST: Post breast conserving surgery irradiation: Radiation therapy is administered within 1 year (365 days) of diagnosis for women under age 70 and receiving breast conserving surgery for breast cancer (Accountability Measure - Released Fall 2008)	90.0%	86.8%	88.6%	91.8%	NA	NA	91.0%
MAC: Adjuvant chemotherapy: Combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1cNoMo, or Stage II or III hormone receptor negative breast cancer (Accountability Measure - Released Fall 2008)	NA	92.9%	92.1%	93.5%	NA	NA	92.0%
Colorectal Cancer							
ACT: Adjuvant chemotherapy: Adjuvant chemotherapy is considered or administered within 4 months (120 days) of diagnosis to patients under age 80 with AJCC III (lymph node positive) colon cancer (Accountability Measure - Released Fall 2008)	NA	90.0%	97.7%	93.0%	NA	NA	80.0%
12 RLN: Surgical resection includes at least 12 lymph nodes: At least 12 regional lymph nodes are removed and pathologically examined for resected colon cancer (Quality Improvement - Released Fall 2008)	85.0%	90.5%	89.1%	87.8%	NA	NA	95.0%
Rectal Cancer							
RECRCT: Pre-operative chemo and radiation are administered for clinical AJCC T3N0, T4N0, or Stage III; or Postoperative chemo and radiation are administered within 180 days of diagnosis for clinical AJCC T1-2N0 with pathologic AJCC T3N0, T4N0, or Stage III; or treatment is considered; for patients under the age of 80 receiving resection for rectal cancer (Quality Improvement - Released Spring 2015)	85.0%	86.1%	84.9%	84.6%	NA	NA	100.0%

	NCDB Target	CoC State of Texas Performance Rate	CoC Census Region (West) Performance Rate	All CoC Programs Performance Rate	Baylor Scott & White – McKinney Performance Rate		
					2015 Forward	Diagnosis Year 2014 (CoC)	2013* 2014* 2015**
Gastric							
G15RLN: At least 15 regional lymph nodes are removed and pathologically examined for resected gastric cancer (Quality Improvement - Released Fall 2014)	80.0%	87.3%	88.9%	89.4%	NA	NA	NA
Non-Small Cell Lung							
10RLN: At least 10 regional lymph nodes are removed and pathologically examined for AJCC Stage 1A, 1B, IIA, and IIB resected NSCLC (Surveillance Measure - Released Fall 2014)	NA	39.4%	37.1%	38.9%	NA	NA	0.0%
LNoSurg: Surgery is not first course of treatment for cN2, M0 cases (Quality Improvement)	85.0%	90.2%	91.2%	90.6%	NA	NA	100.0%
LCT: Systemic chemotherapy is considered or administered within 4 months to the day pre-operatively or day of surgery to 6 months postoperatively or surgically resected cases with pathologic lymph node positive (pN1) and (pN2) NSCLC (Quality Improvement - Released Fall 2014)	85.0%	80.5%	84.7%	87.8%	NA	NA	NA
Cervix							
CBRR: Use of brachytherapy in patients treated with primary radiation with curative intent in any stage of cervical cancer (Surveillance Measure - Released Spring 2015)	NA	74.2%	69.8%	72.1%	NA	NA	NA
CERRT: Radiation therapy completed within 60 days of initiation of radiation among women diagnosed with any stage of cervical cancer (Surveillance Measure - Released Spring 2015)	NA	79.6%	78.6%	77.9%	NA	NA	NA
CERCT: Chemotherapy administered to cervical cancer patients who received radiation for Stages IB2-IV cancer (Group 1) or with positive pelvic nodes, positive surgical margin, and/or positive parametrium (Group 2) (Surveillance Measure - Released Spring 2015)	NA	88.7%	86.7%	86.6%	NA	NA	NA
Endometrium							
ENDLRC: Endoscopic, laparoscopic, or robotic performed for all endometrial cancer (excluding sarcoma and lymphoma), for all stages except Stage IV (Surveillance Measure- Released Fall 2015)	NA	54.9%	54.6%	60.6%	NA	NA	0.0%
ENDCTR: Chemotherapy and/or radiation administered to patients with Stage IIIC or IV endometrial cancer (Surveillance Measure - Released Fall 2015)	NA	74.8%	72.6%	77.8%	NA	NA	NA
Ovary							
OVSAL: Salpingo-oophorectomy with omentectomy, debulking/cytoreductive surgery, or pelvic extenteration in Stages I-IIIC ovarian cancer (Surveillance Measure - Released Fall 2015)	NA	63.9%	64.0%	71.2%	NA	NA	NA
Bladder							
BL2RLN: At least 2 lymph nodes are removed in patients under 80 undergoing partial or radical cystectomy (Surveillance Measure - Released Spring 2016)	NA	87.3%	88.9%	89.4%	NA	NA	NA

*Source: Data is pending results by the Rapid Quality Reporting Process via the National Cancer Data Base.

**The facility did not have data to measure these metrics.



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