Bringing the fight to Cancer.

2016 Annual Report





Quality Study

Adherence to Adjuvant System Therapy Following Primary Surgery in Stage II Breast Cancer Patients: Baylor Scott & White Medical Center – Carrollton 2013-2014

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 metaanalysis¹¹ 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 -Carrollton from 2013-2014.

Methods

analysis:

- recommended.

Using the Baylor Scott & White Health North Texas Cancer Registry data, all stage II breast cancer cases receiving primary surgery (lumpectomy or mastectomy) at Baylor Scott & White - Carrollton from 2013-2014 were compared to the evaluation and treatment guidelines published by the National Comprehensive Cancer Network (NCCN). Stage Il breast cancer patients were identified using the Pathology AJCC stage code and filtered by histology codes (85003, 85203, 85223). The cancer directed surgery code provided by the cancer registry identified lumpectomies and mastectomies. The following results provide 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

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

2. Following mastectomy, radiation therapy

3. ER Positive and PR Positive/Negative 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

Baylor Scott & White – Carrollton encountered eight primary surgeries of which five were lumpectomies and three were mastectomies. In those patients receiving primary surgery, 50 percent (4) were 51 years of age or above and 87.5 percent (7) were White. Divided by AJCC stage treated at Baylor Scott & White – Carrollton, 75 percent (6) were IIA and 25 percent (2) were IIB.

Treatment following Primary Surgery

Of those receiving a lumpectomy:

- > Four (80 percent) were ER Positive and PR Positive/Negative tumors.
- > One (20 percent) was an ER Negative and PR Negative tumor.

All lumpectomy ER Positive and PR Positive/ Negative patients received adjuvant systemic therapy with the majority receiving hormone therapy and radiation. The lumpectomy patient with ER Negative and PR Negative status did not receive adjuvant chemotherapy or radiation therapy due to an elevated age of 90.

Of those receiving mastectomies:

> Three (100 percent) were ER Positive and PR Positive/Negative tumors.

Of the mastectomy patients with ER Positive and PR Positive/Negative cancers, one received surgery only. The majority of mastectomy patients with ER Positive and PR Positive/Negative status received hormone therapy with chemotherapy. Of note, the patients who received surgery had several medical comorbidities.

According to the NCCN guidelines, radiation therapy is recommended following lumpectomy. The majority of patients receiving a lumpectomy at Baylor Scott & White - Carrollton received radiation following surgery (80 percent). In addition, no lumpectomy patients with ER Negative and PR Negative status received hormone therapy. The guidelines also strongly recommend that mastectomy patients receive radiation therapy following surgery. However, only 33.33 percent received radiation with the majority receiving hormone therapy. This finding may be due to patient co-morbidities, such as age and health status, and/or patient informed decision making.

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

Of all stage II breast cancer patients treated at Baylor Scott & White – Carrollton, two patients presented with ER Positive and PR Positive/ Negative Status with HER2 Positive expression. One patient received a lumpectomy and one patient received a mastectomy with reconstruction. The lumpectomy patient received a combination of radiation, chemotherapy and hormone therapy in addition to surgery. The mastectomy patient refused the recommended combination of chemotherapy, radiation therapy and hormone

therapy in addition to surgery. The NCCN guidelines recommend that patients with ER Positive and/or PR Negative tumors with HER2 positive expression receive adjuvant chemotherapy followed by endocrine therapy. One of the two patients received chemotherapy in combination with hormone 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 – Carrollton, one patient presented with ER Negative and PR Negative tumor status with Positive or Negative HER2 expression. The patient received a lumpectomy. The patient did not receive adjuvant therapy due to her elevated age of 90. Given that hormone receptor status was negative for this patient, it was not recommended that she receive 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. The patient who received surgery only was of an age greater than 70 which aligns with NCCN guidelines.

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.

Overall, the analysis demonstrates that Baylor Scott & White – Carrollton is in accordance with the examined NCCN guidelines for treatment following primary surgery in stage II breast cancer patients.

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Cancer Baylor Sco

SCREENING T

| Breast |
|--------|
| Colon |
| Skin |
| |

Low-Dose CT L

Cancer Screenings

Baylor Scott & White Medical Center – Carrollton 2016

| /PE | NUMBER OF 2016 SCREENINGS | NUMBER AT RISK | CANCERS DIAGNOSED |
|-----|------------------------------|-------------------|----------------------|
| | 6,383 | 652 | 41 |
| | 1,281 | 406 | 15 |
| | 72 | 10 | 0 |
| Ing | 47 | 11 | 15 |



| | NCDB Target | CoC State of Texas Performance Rate | CoC Census Region (West) Performance Rate | All CoC Programs Performance Rate | Baylor Scott & White – Carrollton Performance Rate | | |
|--|-----------------|--|---|--|---|--------|--------|
| Breast Cancer | 2015 Forward | Diagnosis Year 2014 (CoC) | | 2013* | 2014* | 2015** | |
| BCS: Breast conservation surgery rate for women with AJCC clinical stage 0, I, or II breast cancer | NA | 54.0% | 57.0% | 64.0% | 81.0% | 80.0% | 93.0% |
| 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% | 96.0% | 100.0% | 97.0% |
| 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% | 100.0% | 100.0% | 100.0% |
| MASTRT: 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% | 100.0% | 100.0% | 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% | 100.0% | 100.0% | 94.0% |
| 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% | 100.0% | 100.0% | 100.0% |
| 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% | 100.0% | 100.0% | 100.0% |
| 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% | 100.0% | 100.0% | 86.0% |
| 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% |

Gastric

G15RLN: At leas resected gastric

Non-Small Cell

10RLN: At least AJCC Stage 1A,

LNoSurg: Surge

LCT: Systemic operatively or day lymph node posi

Cervix

CBRRT: Use of any stage of cerv

CERRT: Radiation diagnosed with a

CERCT: Chemot Stages IB2-IV car positive parametr

Endometrium

ENDLRC: Endos sarcoma and lymp

ENDCTRT: Cher endometrial canc

Ovary

OVSAL: Salpin exteneration in S

Bladder

BL2RLN: At leas cystectomy (Surv

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

Cancer Registry

| | NCDB Target | CoC State of Texas Performance Rate | CoC Census Region (West) Performance Rate | All CoC Programs Performance Rate | Baylor Scott & White – Carrollto Performance Rate | | Carrollton te |
|--|-----------------|--|---|--|--|--------|------------------|
| | 2015 Forward | Diagno | osis Year 2014 | s Year 2014 (CoC) | | 2014* | 2015** |
| st 15 regional lymph nodes are removed and pathologically examined for cancer (Quality Improvement - Released Fall 2014) | 80.0% | 87.3% | 88.9% | 89.4% | NA | NA | NA |
| Lung | | | | | | | |
| 10 regional lymph nodes are removed and pathologically examined for 1B, IIA, and IIB resected NSCLC (Surveillance Measure - Released Fall 2014) | NA | 39.4% | 37.1% | 38.9% | 0.0% | 0.0% | 0.0% |
| ry is not first course of treatment for cN2, M0 cases (Quality Improvement) | 85.0% | 90.2% | 91.2% | 90.6% | NA | NA | NA |
| chemotherapy is considered or administered within 4 months to the day pre- of surgery to 6 months postoperatively or surgically resected cases with pathologic tive (pN1) and (pN2) NSCLC (Quality Improvement - Released Fall 2014) | 85.0% | 80.5% | 84.7% | 87.8% | NA | NA | 100.0% |
| | | | | | | | |
| brachytherapy in patients treated with primary radiation with curative intent in rical cancer (Surveillance Measure - Released Spring 2015) | NA | 74.2% | 69.8% | 72.1% | NA | NA | NA |
| on therapy completed within 60 days of initiation of radiation among women ny stage of cervical cancer (Surveillance Measure - Released Spring 2015) | NA | 79.6% | 78.6% | 77.9% | NA | NA | NA |
| therapy administered to cervical cancer patients who received radiation for incer (Group 1) or with positive pelvic nodes, positive surgical margin, and/or rium (Group 2) (Surveillance Measure - Released Spring 2015) | NA | 88.7% | 86.7% | 86.6% | NA | NA | NA |
| | | | | | | | |
| scopic, laparoscopic, or robotic performed for all endometrial cancer (excluding ohoma), for all stages except Stage IV (Surveillance Measure- Released Fall 2015) | NA | 54.9% | 54.6% | 60.6% | NA | 0.0% | NA |
| notherapy and/or radiation administered to patients with Stage IIIC or IV cer (Surveillance Measure - Released Fall 2015) | NA | 74.8% | 72.6% | 77.8% | NA | NA | NA |
| | | | | | | | |
| go-oophorectomy with omentectmy, debulking/cytoreductive surgery, or pelvic tages I-IIIC ovarian cancer (Surveillance Measure - Released Fall 2015) | NA | 63.9% | 64.0% | 71.2% | NA | 100.0% | NA |
| | | | | | | | |
| st 2 lymph nodes are removed in patients under 80 undergoing partial or radical veillance 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.



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