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A National Cancer Database Study on Intra-Operative Radiation Therapy in Breast Cancer Patients: Does Socioeconomic Status or Race Correlate with Cure?

Jennifer Son[1*], Laurel Mulder[1] and Andrea Madrigrano[2]

[1]*Department of Surgery, Rush University Medical Center, Chicago, USA*

[2]*Division of Oncology, Department of Surgery, Rush University Medical Center, Chicago, USA*

[*]**Corresponding author:** Jennifer Son, Department of Surgery, Rush University Medical Center, Chicago, USA, Tel: 3120426510; Fax: 3129422867; E-mail: jennifer_d_son@rush.edu

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Abstract

Background: Minority women with breast cancer more commonly have poorer outcomes and survival rates. Disparities are multifactorial. It is possible that poor outcomes in minority groups are related to aspects of care such as Intra-Operative Radiation Therapy (IORT). Our study aims to explore whether minority groups who received IORT vs. External Beam Radiation Therapy (EBRT) have poorer outcomes in comparison to non-minorities.

Methods: A retrospective review of data from the National Cancer Database (NCDB) from 2004-2015 was conducted on breast cancer patients who received IORT and EBRT. Multiple demographic variables were examined. Outcomes variables included readmission within 30 days, 30-day mortality, 90-day mortality, and long term survival.

Results: Patients who underwent IORT were generally older than those who underwent non-IORT radiation (66 years of age versus 60; $p<0.001$). Fewer black patients underwent IORT compared to white patients ($p<0.001$). There was no significant difference between patients who underwent IORT and those who underwent non-IORT radiation on 30-day or 90-day mortality, ($p>0.99$ and $p=0.45$, respectively).

Discussion: Race, education, and socioeconomic status all appeared to play a role in the choice of IORT vs. EBRT. However, it does not appear that this affected mortality.

Keywords: Breast cancer; Intra-operative radiation; Disparities; Survival; Radiation therapy

Introduction

In women, breast cancer is the most commonly diagnosed cancer and is the second leading cause of cancer death [1]. Minority women with breast cancer more commonly have poorer outcomes and survival rates [2]. Some studies show that African American women are diagnosed at an earlier age and at a higher tumor stage, tumor size, and tumor grade [3]. African American women also had more receptor-negative tumors and more positive lymph nodes at diagnosis than did Caucasian women. Some studies show there is a decrease in the utilization of radiation therapy across monitory groups.

There are many aspects to the treatment of breast cancer patients, and radiation therapy is an essential part of the treatment plan to prevent local tumor recurrence. Breast-Conserving Therapy (BCT) with radiation is commonly preferable for patients with early-stage breast cancer because survival is equivalent when compared to total mastectomy [4]. Radiation can be delivered to the whole breast daily over a period of 5-6 weeks. This can be inconvenient to many patients due to the long-distance travel to a radiation center, increase age, time, and socioeconomic status [5,6]. Additionally, radiating the entire breast as opposed to just the lumpectomy cavity, can also have some side effects and risks including erythema, edema, skin breakdown, cardiotoxicity, and pulmonary fibrosis [7,8].

A study by Du et al., showed that between 1992 and 2002, although breast conserving therapy increased, the percentage of patients who received concomitant radiation therapy decreased over time. This study also found that African American women were less likely to receive radiation therapy after BCT compared to Caucasian women. This decrease in radiation therapy is not just seen in breast cancer, but also in patients with prostate cancer with both studies showing a greater disparity in minority groups [9]. Observational studies show that receiving BCT without radiation therapy decreases survival [10].

Intra-Operative Radiation Therapy (IORT) is becoming increasingly more common with its ability to deliver radiation directly to the tumor bed at a higher dose [4]. Consensus for IORT suitability include tumors less than 3 cm, node-negative breast cancers, negative surgical margins, and patients older than 50 years-old. It is delivered into the lumpectomy cavity and before wound closure [5]. IORT offers many advantages including patient compliance, decreased irradiation to healthy organs, and decreased skin toxicity, decreasing patient readmission rates and thus possibly affecting complications and mortality.

It is possible that poor outcomes in minority groups are related to aspects of care such as IORT. Our study aims to explore whether minority groups who received IORT *vs.* External Beam Radiation

Therapy (EBRT) have poorer outcomes in comparison to non-minorities.

Methods

A retrospective review of data from the National Cancer Database (NCDB) was conducted on breast cancer patients who received IORT and EBRT. Data were first filtered to exclude all patients who had metastases (or unknown metastases status) at diagnosis (129,046), all men (21,995), and any patients who did not have IORT or beam radiation or radioactive implants after surgery (1,234,502). Additionally, the study was limited to those who had breast conservation therapy. A total of 1,186,535 cases were examined. Of these patients, 4,583 had IORT, and 1,181,952 had non-IORT beam radiation or radioactive implants.

Baseline variables included age, race, insurance status, income (2000 and 2012), education (2000 and 2012), geographical location (2003 and 2013), Charlson score, tumor grade, tumor size, and whether regional nodes were positive. Income data was only available for the years 2000 and 2012 and geographical location data was only available for the years 2003 and 2013. Histology was missing over 99.96% of data and so could not be used. TNM clinical and pathological staging were also missing large amounts of data (46% and 39%, respectively) and could not be used. Outcomes variables included readmission within 30 days, 30-day mortality, 90-day mortality, and long term survival. To determine whether there were any differences between the two groups (IORT and non-IORT radiation), Chi square tests were conducted on categorical variables and Wilcox Mann Whitney tests were conducted on ordinal variables. Kaplan Meier analysis was used to examine whether there were differences in survival between patients who received IORT and those who did not. Due to the number of hypothesis tests among baseline variables, the False Discovery Rate (FDR) was controlled at 0.05 using a Benajmini-Hochberg correction.

All analyses were conducted in R 3.3.2. IRB approval by Rush University Medical Center was obtained prior to starting our research.

Results

A total of 1,186,535 cases were examined. Of these patients, 4,583 had IORT, and 1,181,952 had non-IORT beam radiation. Patients who underwent IORT were generally older (median=66) than those who underwent non-IORT radiation (median=60; p<0.001).

Furthermore, race played a role, with fewer black patients and more white patients undergoing IORT (p<0.001). There was a different pattern of race for patients who underwent IORT when compared to those who underwent non-IORT radiation, with fewer black patients and more white patients undergoing IORT (p<0.001) (Table 1).

	Non-IORT	IORT
Asian or Pacific Islander	3% (37,727)	3% (154)
Black	11% (127,908)	8% (384)
Other or Unknown	2% (22,345)	2% (79)
White	84% (993,972)	87% (3,966)

Table 1: Percentage (number) of cases in racial groups by IORT.

Fewer patients with government insurance (including Medicare and Medicaid) underwent IORT compared to patients with private insurance undergoing IORT (p<0.001) (Table 2). Patients who underwent IORT lived in zip codes with higher incomes when compared to those who underwent non-IORT radiation; this was true with the 2000 cohort as well as the 2012 cohort (p<0.001) for both (Table 3). Patients who underwent IORT lived in zip codes with higher educational attainment when compared to those who underwent non-IORT radiation; this was true with the 2000 cohort as well as the 2012 cohort (p<0.001) for both (Table 4). Patients who underwent IORT were more likely to live in counties of metro areas when compared to those who underwent non-IORT radiation, who were more likely to live in urban or rural counties; this was true with the 2003 cohort as well as the 2013 cohort (p<0.001 and p=0.001, respectively). Patients who underwent IORT had slightly higher Charlson scores when compared to those who underwent non-IORT radiation suggesting they had more comorbidities (p<0.001).

	Non-IORT	IORT*
Government Insurance	40% (467,120)	54% (2,434)
Private Insurance	58% (678,220)	46% (2,075)
Uninsured	2% (21,279)	1% (37)
*Percentages add to 101 due to rounding.		

Table 2: Percentage (%) of cases in insurance status groups by IORT.

2000	Non-IORT	IORT
Income<$30,000	10% (114,693)	8% (353)
$30,000-$35,999	15% (173,195)	13% (579)
$36,000-$45,999	27% (306,064)	24% (1,029)
$46,000 or more	48% (549,568)	55% (2,411)
2012	**Non-IORT***	**IORT**
Income<$38,000	14% (162,083)	10% (459)
$38,000-$47,999	21% (242,608)	18% (821)
$48,000-$62,999	27% (316,127)	25% (1,121)
$63,000 or more	39% (452,747)	47% (2,164)
*Percentages add to 101 due to rounding.		

Table 3: Percentage (%) of people in patients zip codes with particular incomes.

2000	Non-IORT	IORT
29% or more	13% (147,416)	12% (516)
20% – 28.9%	21% (235,068)	18% (788)
14% – 19.9%	23% (267,940)	20% (893)
Less than 14%	43% (492,991)	50% (2,172)
2012	**Non-IORT**	**IORT***
29% or more	13% (157,291)	12% (530)

20% – 28.9%	23% (271,444)	22% (1,002)
14% – 19.9%	34% (396,041)	32% (1,440)
Less than 14%	30% (349,235)	35% (1,593)
*Percentages add to 101 due to rounding.		

Table 4: Percentage (%) of people in the patients zip codes who did not graduate high school by IORT.

Patients who underwent IORT were less likely to be readmitted within 30 days when compared to those who underwent non-IORT radiation, with an OR of 2.18 (95% CI: 1.80-2.63; p<0.001) (Table 5). The initial hypothesis of decreased readmission rates for those patients who underwent IORT was correct, however there was no significant difference between patients who underwent IORT and those who underwent non-IORT radiation on 30-day or 90-day mortality, (p>0.99 and p=0.45, respectively). Kaplan Meier analysis indicated that patients who had IORT survived significantly longer than those who underwent non-IORT radiation (p=0.03); however, the clinical significance is unclear. For example, in the non-IORT group, percent survival at 12 month was 99.5% compared to 99.3% for the IORT group. However, there was a clinical significance at 144 months with the non-IORT group having a percent survival of 72.8% compared to 78.1% for the IORT group.

	Non-IORT	**IORT**
No readmission within 30 days	95% (1,080,998)	98% (4,438)
Readmission within 30 days	5% (59,396)	2% (112)

Table 5: Percentage (number) of cases: 30-day readmission by IORT.

Discussion

Minority women with breast cancer have poorer outcomes and survival rates. This study chose to investigate and compare IORT with EBRT and demographic trends. Our results of the National Cancer Database showed that disparities still exist in treatment of breast cancer. We do see that more white patients, insured patients, and patients living in high-income and higher-education zip codes chose to undergo IORT compared to EBRT. However, this does not appear to have affected mortality. While it is certainly a possibility that minority women are diagnosed at a greater stage and thus are not eligible for IORT, previous studies suggesting lack of access to IORT can also affect their decision in receiving this modality. Prior studies have demonstrated that rates of breast conservation and radiation therapy compliance are inversely related to patients' proximity to a radiation facility, specifically, 63% of patients travel more than 2 miles to a radiation center [11,12]. A total of 1,234,502 patients were excluded because they did not get any form of radiation and 1,186,535 of women who received breast conservation therapy received radiation suggesting that greater than 50% chose to undergo mastectomy or were not compliant with radiation. Thus having more access to IORT therapy can increase compliance to treatment. Additionally, as is seen in our study, 30-day readmission rates for those receiving IORT were much lower than traditional radiation therapy. This can be from the effects of traditional radiation therapy or from patient comorbidities. Having IORT for all can decrease re-admission rates for all breast cancer patients.

This study has several limitations. First, we do not have information on patients' personal or cultural preferences. Therefore, we cannot say whether the ethnic differences in the receipt of breast conserving surgery with conventional radiation or IORT might be explained by the differences in insurance, income, and preferences. We also could not control for patient factors that led to the selection of a specific treatment such as, functional status, and individual preferences. We also do not have information on mammography-detected early-stage tumors, which may vary between racial/ethnic groups. And finally, we lacked information on the availability of IORT at the treatment centers, TNM stage and tumor subtype. Thus to reach a meaningful conclusion, indication, choice, and stage should be included.

In spite of marked advances in breast cancer, disparities persist in access to these modalities. As some studies show, there is a decline in women choosing radiation therapy, with the larger gap existing in minority women. Thus, having access to IORT in some communities can help increase compliance among this group of patients [4-6]. Breast cancer requires multidisciplinary team collaboration and thus we must ensure that all minorities have equal access.

In conclusion, it is increasingly important to address disparities as the population becomes more diverse and to understand the wide range of factors that contribute to them such as socioeconomic and educational status. Further studies are necessary to address other disparities that exist in the treatment of breast cancer and how we can work to provide equal care for all.

Conflict of Interest

The authors whose names are listed certify that we have no affiliations with or involvement in any organization or entity with any financial interest or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

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