

Partial Breast Irradiation

A longitudinal study of symptoms and quality of life

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BACKGROUND: In many women with early-stage breast cancer, breast-conserving surgery (BCS) with partial breast irradiation (PBI) has similar overall survival and local recurrence rates compared to BCS with whole-breast irradiation (WBI). A better understanding of the quality of life (QOL) outcomes during and following BCS with PBI versus BCS with WBI is needed.

OBJECTIVES: This study was conducted to examine symptoms, symptom distress, cosmesis, QOL, and perceived body image in women during and after BCS with PBI.

METHODS: A convenience sample of 31 women completed self-reports pre- and post-PBI over six months. Descriptive statistics and repeated-measures analysis were performed at baseline and three times post-PBI.

FINDINGS: Most women reported satisfaction with body image and good QOL, despite a small decline in social well-being. Fatigue and mild to moderate symptom distress persisted over time.

KEYWORDS

breast cancer; quality of life; radiation therapy; body image; partial breast irradiation

DIGITAL OBJECT IDENTIFIER

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WITH MORE THAN THREE MILLION BREAST CANCER SURVIVORS, it is necessary to identify and understand treatment-related sequelae that affect quality of life (QOL) as therapy evolves (National Cancer Institute, 2016). Radiation therapy with breast-conserving surgery (BCS) has been an equivalent alternative to mastectomy for regional control of the cancer (Fisher et al., 1995; National Institutes of Health, 1991; Veronesi et al., 2001). Whole-breast irradiation (WBI) has been the predominant approach, but the treatment schedule for WBI (i.e., five days per week for six weeks) can be challenging; as a result, some women chose mastectomy as the primary breast therapy (Katie Lee & Knobf, 2015; Lee & Knobf, 2016). Compared to mastectomy, BCS with WBI may be associated with increased use of resources and may negatively affect overall QOL (Kawase et al., 2012; Shah, Lanni, et al., 2013; Whelan, Levine, Julian, Kirkbride, & Skingley, 2000).

Partial breast irradiation (PBI) was explored as an alternative to WBI in an effort to deliver irradiation to a limited area of the breast area near the original tumor site (Swanson & Vicini, 2008) and was found to provide equal benefit, fewer side effects, and improved QOL (Gage et al., 1995; Polgár et al., 2007, 2017; Shah, Vicini, Wazer, Arthur, & Patel, 2013; Smith et al., 2009; Smith, Lee, Turner, Carter, & Haffty, 2000).

The potential benefits of PBI are the accelerated delivery and reduction of radiation exposure to adjacent organs, such as the heart, lungs, and skin (Shah, Vincini, et al., 2013). PBI can be delivered by brachytherapy with multicatheter or balloon catheter devices, implanted radiation sources placed intra- or postoperatively, or external beam therapy (most commonly, three-dimensional conformal external beam radiation therapy [3DCRT]) (Njeh, Saunders, & Langton, 2010; Shaitelman & Kim, 2013; Skowronek, Wawrzyniak-Hojczyk, & Ambrochowicz, 2012).

In the postoperative period following BCS, accelerated PBI using brachytherapy or 3DCRT is typically delivered in high-dose fractions twice daily for about five days (Njeh et al., 2010; Shah, Lanni, et al., 2013; Shaitelman & Kim, 2013; Skowronek et al., 2012; Swanson & Vicini, 2008). Effectiveness, risk, and side effect profile are still under investigation for intraoperative accelerated PBI (Correa et al., 2017).

In 2009, the American Society for Radiation Oncology (ASTRO) issued a consensus statement with recommendations for use of PBI (Smith et

al., 2009). Clinical trials supported these recommendations (Antonucci et al., 2009; Ferraro et al., 2012; Livi et al., 2015; Polgár et al., 2007; Shah et al., 2011; Strnad et al., 2016; Wobb et al., 2016). Subsequently, ASTRO expanded recommendations to include younger women and people with low-risk ductal carcinoma in situ (Correa et al., 2017).

The side effects most commonly experienced by women who received WBI include breast swelling, heaviness, skin changes

(erythema during treatment, subsequent pigment changes), and fatigue. Contour changes of the breast and less favorable cosmetic outcomes, including atrophy and deformity, have been reported in some women (Runowicz et al., 2016). Although many breast changes resolve during the first few months post-treatment, some may persist for as long as a year or more (Knobf & Sun, 2005; Polgár et al., 2017). Fatigue, the most prevalent symptom associated with radiation therapy (Knobf & Sun, 2005), interferes with QOL (Irvine, Vincent, Graydon, & Bubela, 1998) and may persist for years (Gélinas & Fillion, 2004).

Women who were treated with BCS with PBI reported less fatigue than those treated with WBI (Albuquerque et al., 2012; Pérez, Schootman, Hall, & Jeffe, 2017), with better QOL and functioning (Albuquerque et al., 2012; Wadasadawala et al., 2009). Most women reported good or excellent cosmesis following PBI (Hill-Kayser, Vachani, Hampshire, Di Lullo, & Metz, 2012), as well as better cosmesis compared to women who had mastectomy (Kim et al., 2015). Cosmesis and functional ability are correlated (Sneeuw et al., 1992b) and positively affect QOL (Heil et al., 2011; Volders et al., 2017). Compared to WBI, PBI is associated with less severe skin irritation (Pérez et al., 2017). A Cochrane review reported conflicting evidence about side effects with PBI related to worse cosmetic outcomes (physician-reported) and fibrosis; although acute skin toxicity appeared better, late skin toxicity and breast pain did not differ between PBI and WBI (Hickey, Lehman, Francis, & See, 2016).

Cross-sectional study findings on BCS with PBI are limited because of their design (not prospective and longitudinal), which consists of patients reporting symptoms, cosmesis, and QOL during and after PBI. The purpose of the current study was to describe symptoms and symptom distress, cosmetic outcomes using a reliable and valid questionnaire, QOL, and perceived body image of women during and following BCS with PBI.

Methods

A prospective, longitudinal study was conducted over six months and examined symptoms, symptom distress, cosmesis, QOL, and body image in women during and after BCS with PBI. A convenience sample of 31 women aged 18 years or older who understood English, were diagnosed with stage 0–II breast cancer, had BCS, and were scheduled for PBI were recruited at Yale Cancer Center in New Haven, Connecticut. Nurses and radiation oncologists informed the patients about the study. A trained research assistant was present at the radiation oncology clinic and checked in daily with the radiation oncologists and nurses about potential patients. A nurse practitioner in the clinic was also instrumental and supportive in recruiting participants for the study. Institutional review board approval was obtained from Yale Cancer Center’s institutional review board, and written consent was received from all participants.

TABLE 1.
SAMPLE CHARACTERISTICS (N = 31)

| CHARACTERISTIC | \bar{x} | SD | RANGE |
|-------------------------|-----------|-------|-------|
| Age (years) | 58.5 | 11.97 | 44–85 |
| CHARACTERISTIC | n | | |
| Ethnicity | | | |
| White | | | 29 |
| Black | | | 1 |
| Hispanic | | | 1 |
| Education | | | |
| High school | | | 6 |
| Some college | | | 8 |
| Bachelor’s degree | | | 7 |
| Graduate degree | | | 7 |
| Other | | | 3 |
| Marital status | | | |
| Married | | | 19 |
| Not married | | | 3 |
| Widowed | | | 9 |
| Employment | | | |
| Full- or part-time | | | 19 |
| Retired or not employed | | | 12 |
| Income (\$) | | | |
| Less than 40,000 | | | 11 |
| 40,000–60,000 | | | 8 |
| More than 60,000 | | | 10 |
| Missing data | | | 2 |

Data Collection and Measurement

Self-reported data were collected by trained research assistants at baseline (i.e., prior to the initiation of PBI) and at one month, three months, and six months post-PBI.

The PBI Symptom Distress Questionnaire is an investigator-designed questionnaire used to assess the presence and perceived distress of six symptoms (breast skin changes, sensations, texture changes, swelling, pain, and sleep difficulties) associated with breast irradiation (Knobf & Sun, 2005). Distress ranges from 1 (not at all bothered) to 5 (extremely bothered), with higher scores indicating greater distress.

The 10-item Body Image Scale (BIS) was designed specifically to assess distress, and answers range from 0 (not at all) to 3 (very much). Total scores range from 0–30, with higher scores reflecting more distress. The BIS was tested with 682 women with breast cancer, showing high reliability (Cronbach alpha = 0.93) and demonstrating sensitivity to change ($p < 0.001$) (Hopwood, Fletcher, Lee, & Al Ghazal, 2001).

The Breast Cancer Treatment Outcomes Scale (BCTOS) was designed to measure perceived differences in aesthetic and functional outcomes after BCS and irradiation (Kanatats et al., 2012; Stanton, Krishnan, & Collins, 2001). Answers range from 0 (no difference) to 3 (large difference), with higher scores indicating greater perceived difference in outcomes (range = 0–54). The three subscales have good internal consistency: functional status (7 items, Cronbach alpha = 0.91), cosmetic status (8 items, Cronbach alpha = 0.89), and breast-specific pain (3 items, Cronbach alpha = 0.81). Items have demonstrated evidence of predictive validity with their correlation to QOL outcomes; correlation among scales ranged from 0.36–0.52 ($p < 0.0001$)

(Krishnan, Stanton, Collins, Liston, & Jewell, 2001; Stanton et al., 2001).

The 13-item Functional Assessment of Chronic Illness Therapy–Fatigue (FACIT-F) scale was used to rate the frequency of fatigue with daily activities. Answers ranged from 0 (not at all) to 4 (very much), and total scores ranged from 0–52, with higher scores indicating less fatigue. The FACIT-F has good test-retest reliability ($r = 0.9$) and internal consistency (Cronbach alpha = 0.93–0.95) (Webster, Cella, & Yost, 2003; Yellen, Cella, Webster, Blendowski, & Kaplan, 1997).

QOL was measured using the 37-item Functional Assessment of Cancer Therapy–Breast (FACT-B) scale, version 4, which includes four well-being subscales from the FACT–General scale (physical [7 items], social/family [7 items], emotional [6 items], and functional [7 items]), as well as a 10-item breast cancer concerns subscale. Patients rank how true each item has been for the past seven days from 0 (not at all) to 4 (very much), with higher scores indicating better QOL. Psychometric properties are well documented with good test-retest reliability ($r = 0.85$) and internal consistency (Cronbach alpha = 0.9). Subscale Cronbach alpha coefficients ranged from 0.63–0.86 (Brady et al., 1997; Nguyen et al., 2015).

Data Analysis

Data were analyzed with descriptive and repeated-measures analyses at baseline and at three time points post-treatment (one month, three months, and six months) using SAS, version 9.1. The investigators scored the instruments based on instrument instructions. If as many as 15% of items were missing a response for a given instrument, those values were estimated based on

TABLE 2.
SYMPTOMS AND DISTRESS AT 1, 3, AND 6 MONTHS AFTER PARTIAL BREAST IRRADIATION

| SYMPTOM | 1 MONTH (N = 27) | | | 3 MONTHS (N = 26) | | | 6 MONTHS (N = 27) | | | DISTRESS CHANGE (%) | | |
|-----------------------|---------------------|-----------|------|----------------------|-----------|------|----------------------|-----------|------|---------------------|------------|----------------|
| | n | \bar{X} | SD | n | \bar{X} | SD | n | \bar{X} | SD | 1-3 MONTHS | 3-6 MONTHS | p ^b |
| Pain | 10 | 2.88 | 0.64 | 9 | 2.78 | 0.44 | 12 | 3 | 1 | -3.5 | 7.9 | 0.265 |
| Sensation | 20 | 2.15 | 0.75 | 21 | 2.1 | 0.77 | 20 | 2.17 | 0.71 | -2.3 | 3.3 | 0.89 |
| Skin changes | 16 | 2.25 | 0.86 | 8 | 2.125 | 0.64 | 7 | 1.57 | 0.79 | -5.6 | -26.1 | 0.0002 |
| Sleep difficulties | 14 | 2.85 | 0.9 | 14 | 2.64 | 0.92 | 15 | 2.82 | 0.87 | -7.4 | 6.8 | 0.82 |
| Swelling ^a | 9 | - | - | 1 | - | - | 2 | - | - | - | - | - |
| Texture changes | 16 | 2.38 | 0.89 | 16 | 1.62 | 0.65 | 12 | 2.18 | 0.87 | -31.9 | 34.6 | 0.005 |

^a Distress was not analyzed because of the low number reporting.

^b Based on repeated-measures analysis of variance using a mixed model with compound symmetry

Note. The Partial Breast Irradiation Symptom Distress Questionnaire was used to assess the presence and perceived distress of symptoms. Patients rated distress from each symptom from 1 (not at all bothered) to 5 (extremely bothered), with higher scores indicating greater distress.

the average score of other items composing the instrument. The PBI Symptom Distress Questionnaire data were analyzed with descriptive statistics at each time point; BIS, BCTOS, FACIT-F, and FACT-B data were analyzed using the MIXED procedure and compound symmetry. Pairwise comparisons were assessed by adjusting for multiple comparisons with a Bonferroni correction. Because of large ranges at three and six months, the FACIT-F repeated-measures analysis was conducted with and without one outlier.

Results

The mean age of the participants was 62.8 years (range = 44–85 years). Most were non-Hispanic White, married, employed, and had education beyond high school. Table 1 describes the sample.

Symptoms and Symptom Distress

At one month post-PBI, most women (n = 16) reported skin changes, breast sensations, texture changes, and sleep alterations, whereas 9 reported breast swelling and 10 reported pain. Breast sensations, texture changes, sleep alterations, and pain persisted at similar levels across the six months, whereas the reporting of skin changes and breast swelling decreased. Symptom distress was mild to moderate and persisted for six months except for skin changes, which decreased over time (p = 0.0002) (see Table 2).

Body Image

Most women were satisfied with their body image across the six months of study, and no significant change was observed over time (p = 0.7301, f = 0.43). Mean scores at each time point were 2.92 (SD = 4.67) at baseline, 2.42 (SD = 2.33) at one month, 2.46 (SD = 2.74) at three months, and 2.5 (SD = 2.92) at six months.

“Most women were satisfied with their body image across the six months of study.”

Breast Cancer Treatment Outcomes

Mean scores for the BCTOS were low, indicating slight or no difference in functional status, cosmesis, and pain. Mean scores ranged from 11.08 (SD = 6.63) at baseline, 10.13 (SD = 6.8) at one month, 9.21 (SD = 6.75) at three months, and 10.34 (SD = 7) at six months. No statistical difference was observed over time (p = 0.6088, f = 0.61), but most women in the sample reported some difference in breast size, texture, tenderness, pain, sensitivity, scar tissue, and shape compared to baseline. About one-third of women in the sample reported a difference in their ability to lift objects and the fit of their bra after BCS with PBI.

Fatigue

Average fatigue scores for the sample of women were in the top 20% of possible scores on the scale across all time points, indicating a relatively moderate to low level of fatigue with no difference during the six months (p = 0.8128, f = 0.32). A sensitivity analysis in which two outliers were removed did not change the analysis. Data, including outliers, are presented in the current

TABLE 3. FACT-B QUALITY-OF-LIFE SUBSCALE SCORES AND TOTAL SCORE AT EACH TIME POINT

| SUBSCALE | BASELINE (N = 31) | | 1 MONTH (N = 27) | | 3 MONTHS (N = 26) | | 6 MONTHS (N = 27) | | CHANGE (%) | | | p ^a |
|------------------------|----------------------|-------|---------------------|-------|----------------------|-------|----------------------|-------|------------|------------|------------|----------------|
| | \bar{X} | SD | \bar{X} | SD | \bar{X} | SD | \bar{X} | SD | <1 MONTH | 1-3 MONTHS | 3-6 MONTHS | |
| Breast cancer-specific | 27.56 | 4.55 | 27.98 | 3.92 | 27.59 | 5.54 | 27.68 | 4.57 | 1.5 | -1.4 | 0.3 | 0.87 |
| Emotional | 19.37 | 3.58 | 20.26 | 3.86 | 18.98 | 4.44 | 19.59 | 3.28 | 4.6 | -6.3 | 3.2 | 0.039 |
| Functional | 20.22 | 6.39 | 21.07 | 5.87 | 18.52 | 7.09 | 20.59 | 6.1 | 4.2 | -12.1 | 11.2 | 0.29 |
| Physical | 24.54 | 3.63 | 24.96 | 3.68 | 25.12 | 3.06 | 25.44 | 3.57 | 1.7 | 0.6 | 1.3 | 0.42 |
| Social | 25.04 | 3.03 | 24.17 | 3.27 | 21.97 | 4.98 | 22.9 | 4.86 | -3.5 | -9.1 | 4.2 | 0.005 |
| FACT-B total | 116.23 | 16.12 | 118.45 | 16.25 | 112.18 | 17.97 | 116.21 | 16.02 | 1.9 | -5.3 | 3.6 | 0.02 |

^aBased on repeated measures analysis of variance using a mixed model with compound symmetry
FACT-B—Functional Assessment of Cancer Therapy—Breast

Note. Patients ranked how true each item was for the past seven days from 0 (not at all) to 4 (very much). Total scores ranged from 0–148, with higher scores indicating better quality of life.

article. Mean scores were 41.5 (SD = 7.12) at baseline, 41.5 (SD = 9.34) at one month, 40.5 (SD = 8.88) at three months, and 41.7 (SD = 9.97) at six months.

Quality of Life

Overall QOL remained the same over time, but social and emotional well-being subscale scores changed from baseline. Emotional well-being was significantly better at one month post-PBI compared to baseline ($p = 0.039$, $f = 2.92$), with no difference at three and six months. In contrast, social well-being was significantly worse at three and six months compared to baseline ($p = 0.005$, $f = 4.66$) (see Table 3).

Discussion

This prospective, longitudinal study described symptoms, cosmesis, body image, and QOL experienced by women during and following BCS with PBI, an established treatment option instead of mastectomy or WBI for women with early-stage breast cancer (Correa et al., 2017; Jawad et al., 2017; Smith et al., 2009).

Although most women in this study reported persistent symptoms (breast texture changes, sensations, pain, and sleep disturbances) during the six-month period, their symptom distress was mild or moderate. Skin changes were more distressing and prevalent at one month after PBI compared to at three and six months and was the only symptom that improved from baseline. Pérez et al. (2017) and a comprehensive review by Hickey et al. (2016) suggested that short-term skin toxicity may be less severe with PBI versus WBI. Hickey et al. (2016) noted that cosmetic outcomes may be worse longer term with PBI versus WBI. The persistence, timing, and severity (mild to moderate) of symptoms reported in the current study is consistent with the side effects following PBI reported in other studies (Hickey et al., 2016; Pérez et al., 2017).

Fatigue is a prevalent symptom that affects quality of life and can last a year or longer postirradiation (Gélinas & Fillion, 2004; Hickok et al., 2005; Knobf & Sun, 2005; Noal et al., 2011). Albuquerque et al. (2012) reported a decrease in fatigue at six weeks after PBI using the FACT-Fatigue questionnaire, in contrast to the current study's findings of no change over time. However, Pérez et al. (2017), using a vitality subscale to measure fatigue, reported no change over six months, and no differences between women who received PBI versus WBI were reported, which is consistent with the current study's findings. Although persistent, fatigue with PBI diminishes faster and is less severe than fatigue with WBI (Albuquerque et al., 2012; Pérez et al., 2017).

In the current study, women were satisfied with their body image and reported little or no change in cosmesis over six months, which is similar to previous findings (Kim et al., 2015). Baseline responses indicated more variation in satisfaction with body image. Improved perceptions of body image over time may

IMPLICATIONS FOR PRACTICE

- Inform the delivery of quality patient-centered care by understanding the trajectory of symptoms and the influence of treatment on body image and quality of life.
- Educate women who are weighing treatment options for early-stage breast cancer on expected symptoms and outcomes associated with partial breast irradiation (PBI).
- Conduct additional clinical investigation on the social well-being of women receiving treatment with PBI for breast cancer.

be related to the healing of the surgical site. Self-reported body image has been shown to correlate with self-reported cosmesis (Al-Ghazal, Fallowfield, & Blamey, 1999; Kim et al., 2015; Sneeuw et al., 1992b) and with improved QOL and functional ability (Heil et al., 2011; Kim et al., 2015; Sneeuw et al., 1992b; Volders et al., 2017; Waljee et al., 2008). As a result, documenting patient self-reports of cosmesis is important because they may differ from observer ratings (Sneeuw et al., 1992a; Taylor et al., 1995).

In the current study, quality of life was maintained during the six-month period. Similar findings have been reported for QOL using the FACT-B questionnaire (Pérez et al., 2017) and for body image and cosmesis (Al-Ghazal et al., 1999; Heil et al., 2011; Kim et al., 2015; Volders et al., 2017). However, it is unclear why social well-being declined at three and six months. No data were collected on adjuvant therapy; some participants may have been on therapies that interfered with their social relationships and function.

Limitations

Limitations include a small convenience sample, no WBI comparison group, and lack of data on adjuvant therapies. However, the study findings support those of larger trials related to fatigue and QOL (Albuquerque et al., 2012; Pérez et al., 2017), and there was very little attrition during the six months of data collection. Strengths of this study include the longitudinal design and use of well-validated instruments. This study contributes to the evidence about symptoms and related distress, self-reported body image, cosmesis, and QOL following BCS, and during and for six months following treatment for early-stage breast cancer with PBI.

Implications for Clinical Practice

The results reported in this study, albeit from a relatively small sample, are critical in anticipatory guidance for self-management (Johnson, Fieler, Jones, Wlasowicz, & Mitchell, 1997) and could be used to provide concrete information to prepare women for what to expect with PBI treatment over time and to determine strategies for optimal symptom management (Knobf, 2013). Oncology nurses need to be aware of symptom patterns and evidence-based strategies for management. Older and younger women want detailed information about side effects when making treatment decisions for breast cancer; younger women particularly need information about body image and sexuality (Jahraus, Sokolosky, Thurston, & Guo, 2002; Recio-Saucedo, Gerty, Foster,

Eccles, & Cutress, 2016; Wang et al., 2017). Nurses should provide comprehensive information about symptoms and quality of life when discussing treatment options for early-stage breast cancer and related side effects to assist women with their treatment decision-making process. ASTRO evidence-based guidelines for WBI recommend using only hypofractionated WBI for all stages of breast cancer and for women of all ages (Smith et al., 2018). Understanding of the side effects and QOL associated with PBI, the other evidence-based radiation treatment option for women with early-stage breast cancer, is necessary when hypofractionated WBI is unavailable (Smith et al., 2009).

Despite the low to moderate and stable levels of fatigue reported in this study, nurses should continue to provide support and information to women about fatigue mitigation strategies, such as moderate activity (Lipsett, Barrett, Haruna, Mustian, & O'Donovan, 2017; Mitchell et al., 2014) and energy conservation techniques (Barsevick et al., 2004; Sadeghi, Gozali, & Moghaddam Tabrizi, 2016).

Conclusion

The women in this study reported symptoms and QOL for six months during and following PBI for early-stage breast cancer. The findings support evidence of relatively low symptom distress over time, satisfactory body image, and overall good QOL after BCS and PBI. It is important to understand factors that influence QOL and the symptom experience to identify areas for improvement. As a result, future research should examine side effects related to different types of PBI versus hypofractionated WBI with larger samples to evaluate longitudinal trends by targeting different demographic groups and by adjusting for possible time-dependent covariates, including adjuvant chemotherapy and endocrine therapies.

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