Patient-reported outcomes version of the common terminology criteria for adverse events and quality-of-life linear analogue self-assessment in breast cancer patients receiving radiation therapy: single-institution prospective registry

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Abstract

Purpose/objectives: We sought to investigate the impact of patient-reported outcomes version of the common terminology criteria for adverse events (PRO-CTCAE) on overall quality-of-life (QOL) employing linear analogue self-assessment (LASA) in breast cancer (BC) patients undergoing radiation therapy (RT).

Materials/methods: All patients treated with RT for BC with curative intent from 2015 to 2019 at our institution were included. Breast specific PRO-CTCAE and overall QOL LASA questionnaires were administered at baseline, end-of-treatment, 3, 6, 12 months, and then annually. Minimal clinically important difference in overall QOL was a 10-point change in LASA. Hypofractionation was any treatment > 2 Gy per fraction. Mixed models for repeated measures were used to determine the association of PRO-CTCAE and overall QOL LASA.

Results: Three hundred thirty-one (331) patients with a median follow-up of 3.1 years (range 0.4–4.9) were included. Average overall QOL LASA scores were 78.5 at baseline, 79.8 at end-of-treatment, 79.8 at 3 months, 77.1 at 6 months, 79.4 at 12 months, and 79.7 at 24 months. On univariate analysis, patients reporting a grade ≥ 3 PRO-CTCAE had, on average, a 10.4-point reduction in overall LASA QOL (p < 0.0001). On multivariate analysis, not being treated with hypofractionation and higher BMI were predictive for worse overall LASA QOL with a 10-point reduction in LASA for patients reporting a grade ≥ 3 PRO-CTCAE (p < 0.0001).

Conclusions: Patients reporting a grade ≥ 3 PRO-CTCAE experienced statistically significant and clinically meaningful deterioration in overall QOL LASA. Hypofractionation improved QOL while higher BMI predicted for worse QOL. PRO-CTCAE should be integrated into future clinical trials.

Introduction

Adverse events during cancer treatment are recorded using the US National Cancer Institute’s (NCI) Common Terminology Criteria for Adverse Events (CTCAE) [1]. However, symptomatic adverse events are often under-reported by physicians and do not fully represent the...
entirety of the negative impact that cancer treatment has on patients [2, 3].

As a result, patient reported outcomes (PROs) have been developed and provide complimentary information to physician reported measures [4]. In fact, PROs have been shown to predict for overall survival for many different cancers [5–7]. There are numerous tools to measure PROs including the NCI’s Patient-Reported Outcomes Measurement Information System (PROMIS), and LASA that were routinely administered to all breast cancer patients undergoing radiation. The questionnaires were administered to all patients via an online portal or at radiation oncology office visits via tablet at baseline before radiation, end of radiation, 3 months, 6 months, and 12 months after radiation, and then annually. Patients were required to have baseline questionnaires and at least 1 other time point to be included. The current study only looked at the PRO-CTCAE items and overall QOL LASA. The PRO-CTCAE items that were asked on the institution derived questionnaire included anxiety interference, insomnia interference, severity of shortness of breath, shortness of breath interference, severity of cough, concentration interference, sadness, interference of skin burns, severity of difficulty swallowing, decreased appetite interference, how often nauseated, severity of constipation, numbness or tingling in hands or feet interference, and how often loose or watery stools (diarrhea). A patient was considered to have patient-reported treatment-related symptomatic adverse event at each time-point, if she had a score of 3 or higher (‘severe’ or worse) for any breast specific PRO-CTCAE item that was higher than baseline. Over all LASA was scored on the 0–10 scale and transformed to a continuous 0–100 point scale. Minimal clinically important difference in overall QOL is defined, herein, as a 10-point decrease in LASA transformed score [13].

Statistics
Mixed models for repeated measures, controlled for baseline LASA score, was utilized to model the association between overall QOL LASA scores with PRO-CTCAE, socio-demographic, clinical, and treatment covariates. Univariate (UVA) models are presented, and multivariate models were determined utilizing statistically and clinically significant factors to determine ‘best’ model based on Bayes’ Information Criteria (BIC).
Results

Three hundred thirty-one (331) patients with a median follow-up of 3.1 years (range 0.4–4.9) were included. Patient and tumor characteristics are listed in Table 1. Most patients were pT1 (51%), pN0 (64%), ER+ (82%), PR+ (77%), and had invasive ductal carcinoma (85%). Treatment characteristics are listed in Table 2. Patients were typically treated with lumpectomy (75%) followed by whole breast radiation to 40.05 Gy. Most patients (85%) were treated with photons. Three hundred thirty-one patients answered questionnaires at baseline, 255 at end of treatment, 205 at 3 months after treatment, 214 at 6 months after treatment, 128 at 12 months after treatment, and 34 at 24 months after treatment.

PRO-CTCAE of grade ≥2 ("moderate" or worse) above baseline were reported by 75% of patients and grade ≥3 ("severe" or worse) above baseline were reported by 32%. Specific PRO-CTCAE items grade ≥2 or ≥3 above baseline at any time are listed in Table 3. The most common grade ≥2 items were dermatitis (76%), insomnia (40%), and anxiety (32%). The most common grade ≥3 items were dermatitis (33%), insomnia (28%), and concentration (28%).

Average overall QOL LASA scores for all patients did not change significantly over time (p = 0.7). Scores were 78.5 at baseline, 79.8 at end of treatment, 79.8 at 3 months, 77.1 at 6 months, 79.4 at 12 months, and 79.7 at 24 months (Fig. 1). On univariate analysis, increasing BMI and patients who experienced a grade ≥3 ("severe" or worse) PRO-CTCAE reported significantly lower overall QOL LASA score (p ≤ 0.0001 for both) (Table 4). Additionally, patients treated with hypofractionation had improved (higher) overall QOL LASA scores (p = 0.004). On multivariate analysis, hypofractionation improved overall QOL LASA (4.08 points, p = 0.004) and higher BMI led to worse overall QOL LASA (−0.58 points per 1 kg/m² increase in BMI, p < 0.0001). Importantly, patients who reported grade ≥3 ("severe" or worse) PRO-CTCAE were found to have a 10-point drop in their overall QOL LASA score (p < 0.0001) (Fig. 2).

Discussion

We compared PROs using LASA and PRO-CTCAE measures for breast cancer patients receiving radiation treatment in a prospective institutional registry. Our overall QOL LASA scores are consistent with other.

Table 1: Patient and tumor characteristics

| Characteristic                         | n = 331 |
|---------------------------------------|---------|
| Age, years (range)                    | 60 (29–87) |
| BMI (range)                           | 26.8 (17.3–50.7) |
| ECOG                                  |         |
| 0                                     | 219 (66%) |
| 1                                     | 108 (33%) |
| 2                                     | 4 (1%)   |
| Laterality                            |         |
| Right                                 | 163 (49%) |
| Left                                  | 168 (51%) |
| Histology                             |         |
| Invasive ductal                       | 283 (85%) |
| Invasive lobular                      | 13 (4%)  |
| Mixed                                 | 5 (2%)   |
| Other                                 | 30 (9%)  |
| Grade                                 |         |
| 1                                     | 71 (21%) |
| 2                                     | 148 (45%) |
| 3                                     | 111 (34%) |
| Not reported                          | 1 (< 1%) |
| pT stage                              |         |
| T0                                    | 25 (8%)  |
| Tis                                   | 52 (16%) |
| T1                                    | 169 (51%) |
| T2                                    | 63 (19%) |
| T3                                    | 21 (6%)  |
| Not reported                          | 1 (< 1%) |
| Nodal status                          |         |
| Negative                              | 211 (64%) |
| Positive                              | 87 (26%) |
| Not reported                          | 33 (10%) |
| ER positive                           | 271 (82%) |
| PR positive                           | 255 (77%) |
| HER2 positive                         | 33 (10%) |
| TNBC                                  | 27 (8%)  |

Table 2: Treatment characteristics

| Type of surgery                        |          |
|---------------------------------------|----------|
| Lumpectomy                            | 249 (75%) |
| Mastectomy                            | 48 (15%) |
| Other                                 | 34 (10%) |
| Sentinel lymph node biopsy            | 223 (67%) |
| Axillary lymph node dissection        | 71 (21%) |
| Any chemotherapy                      | 129 (39%) |
| Radiation dose median, Gy (range)     | 40.05 (40.05–50.4) |
| Radiation boost median, Gy (range)    | 10 (5.4–10.5) |
| Received boost                        | 131 (40%) |
| Nodal radiation                       | 48 (15%) |
| Hypofractionation*                    | 247 (75%) |
| Treated with photons                  | 281 (85%) |
| Treated with protons                  | 50 (15%) |

* Hypofractionation defined as any treatment > 2 Gy per fraction

BMI, body mass index; ECOG, Eastern Cooperative Oncology Group; ER, estrogen receptor; PR, progesterone receptor; TNBC, triple negative breast cancer
This study supports the use of single item PROs, like LASA, for breast patients receiving radiation therapy. Patients who reported a PRO-CTCAE grade ≥ 3 (‘severe’ or worse) experienced statistically significant and clinically meaningful deterioration in overall QOL based on LASA scale. Additionally, BMI and hypofractionation impact overall QOL.

Our study supports the assertion that single item measures of QOL, like LASA, are useful in breast cancer and correlate well with PRO-CTCAE. Patients who reported grade ≥ 3 (‘severe’ or worse) PRO-CTCAE were found to have a 10-point drop in their overall QOL LASA score (p < 0.0001). As noted, a potential disadvantage of single-item measures, like LASA, is the lack of detail of the factors contributing to a decrease in quality of life [6]. The additional information provided from PRO-CTCAE can help clinicians identify the contributing factors of the decrease QOL that would not be available if LASA was used by itself. This also indicates that LASA may be useful as a screening tool. For example, all patients could be asked overall QOL LASA before each visit and if it indicates a worsening QOL then additional PRO measures like PRO-CTCAE could be used to better define the cause of the worsening QOL. This would help minimize the

| Question                  | PRO-CTCAE Grade ≥ 2 | PRO-CTCAE Grade ≥ 3 |
|---------------------------|---------------------|---------------------|
| Anxiety                   | 108 (32%)           | 51 (15%)            |
| Appetite                  | 27 (8%)             | 9 (3%)              |
| Concentration             | 104 (31%)           | 32 (28%)            |
| Cough                     | 98 (31%)            | 33 (10%)            |
| Insomnia                  | 133 (40%)           | 91 (28%)            |
| Interfere with breath     | 30 (9%)             | 13 (4%)             |
| Nausea                    | 52 (16%)            | 19 (6%)             |
| Sadness                   | 98 (30%)            | 83 (25%)            |
| Severity of breath        | 97 (30%)            | 60 (19%)            |
| Skin                      | 204 (76%)           | 87 (33%)            |
| Swallowing                | 54 (18%)            | 20 (7%)             |
| Tingling                  | 40 (12%)            | 18 (6%)             |

Table 3 PRO-CTCAE Grade ≥ 2 and ≥ 3 at any time

Fig. 1 LASA over time. LASA at each timepoint did not change significantly over time (p = 0.7). EOT, end of treatment
burden of long PRO questionnaires to patients while at the same time remaining useful for clinicians to improve patient care. Another concern is the potential for non-normal distribution of QOL using LASA including floor and ceiling effects. However, research has shown that the utilization of normal distribution theory is acceptable for Likert scale PROs even with floor/ceiling effects [15].

Hypofractionation has become a standard option for breast radiation therapy based on the results of several large randomized trials [16–18]. These trials have demonstrated less toxicity with hypofractionation compared to conventional fractionation [16, 17]. Additionally, hypofractionation is more cost effective compared to conventional fractionation [19]. As a result, the utilization

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**Table 4** Univariate and multivariate analysis showing estimates of LASA point changes

| Variable                      | UVA estimate (95% CI) | P value | MVA estimate (95% CI) | P value |
|-------------------------------|-----------------------|---------|-----------------------|---------|
| Age                           | 0.11 (−0.002 to 0.22) | 0.055   | −0.5515 (−0.74 to −0.36) | <0.0001 |
| Body mass index               | −0.58 (−0.77 to −0.34) | <0.0001 | −0.5515 (−0.74 to −0.36) | <0.0001 |
| Node Positive                 | −1.93 (−4.71 to 0.85) | 0.174   | −1.93 (−4.71 to 0.85) | 0.174   |
| Sentinel lymph node biopsy    | −2.14 (−4.63 to 0.34) | 0.091   | −2.14 (−4.63 to 0.34) | 0.091   |
| Axillary lymph node dissection| −0.44 (−3.36 to 2.48) | 0.766   | −0.44 (−3.36 to 2.48) | 0.766   |
| Boost                         | 1.59 (−0.8 to 3.99)   | 0.191   | 1.59 (−0.8 to 3.99)   | 0.191   |
| Hypofractionation             | 4.08 (1.35–6.81)      | 0.004   | 3.6488 (1–6.3)        | 0.007   |
| Proton                        | 1.14 (−2.05 to 4.34)  | 0.482   | 1.14 (−2.05 to 4.34)  | 0.482   |
| PRO-CTCAE Grade ≥ 3           | −10.41 (−13.57 to −7.25) | <0.0001 | −10.41 (−13.57 to −7.25) | <0.0001 |

CI, confidence interval

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**Fig. 2** Overall QOL LASA and Grade ≥ 3 PRO-CTCAE over time. Overall average QOL LASA at each time point according to patients who reported a grade ≥ 3 (‘severe’ or worse) PRO-CTCAE. Number of patients at each time point is found below the graph. EOT, end of treatment; PRO, patient-reported outcomes
of hypofractionation has become a standard and its use is increasing [20]. In keeping with this, the majority of patients in this study were treated with hypofractionation and were more likely to have better quality of life compared to women treated with conventional fractionation. This is similar to an analysis by Arsenault et al. who reported acute toxicity and PROs in a large randomized trial of conventional radiation versus hypofractionation following breast-conserving surgery for breast cancer [21]. A Breast Cancer Questionnaire, which is a validated instrument measuring quality of life in breast cancer patients, at baseline and 4 weeks after radiation was utilized. Patients randomized to hypofractionation had improved overall quality of life and quality of life attributed to less skin side effects, breast side effects, and improved attractiveness (all p<0.01). Additionally, hypofractionated patients experienced less acute toxicity. Improved quality of life with hypofractionation in this study and ours furthers supports its use in the setting of breast cancer.

In the current study, higher BMI predicted for worse quality of life. Higher BMI has been shown to be associated with worse quality of life in other cancers [22, 23]. Similarly, higher BMI has also been shown to correlate to worse physician reported adverse events [24, 25]. In a study of breast cancer survivors, Anbari et al. used the validated 36-Item Short Form Health Survey to compare quality of life to changes in BMI which showed that a BMI change corresponded to 5 of the 8 domains [26]. However, increasing BMI corresponded to worsening quality of life in only 3 domains including physical functioning (p=0.0052), role limitations related to emotional problems (p=0.0216), and energy/fatigue (p=0.0045). Interestingly, 2 domains, role limitations related to physical functioning and social functioning improved as BMI increased (p=0.0052 and p=0.0014, respectively). These studies suggest the relationship between a patient’s BMI and quality of life is complex and impacts quality of life during treatment and in survivorship. Additional research is needed to better define and explain the interaction.

Other studies have showed that single-item measures correlate well with multi-item measures [10, 27]. For example, Locke et al. investigated single-item LASA versus multi-item in patients with high grade gliomas [10]. Patients were assessed with LASA, the Functional Assessment of Cancer Therapy-Brain (FACT-Br), Profile of Mood States-Short form (POMS-SF), and Symptoms Distress Scale (SDS). They showed that LASA strongly correlated with each of the multi-item instruments and concluded that it might be useful as a screening measure with a general view of quality of life is needed. Similarly, Hubbard et al. performed a survey of providers after implementation of single-item LASA measures for fatigue, pain, and overall quality of life in clinical oncology practices [28]. The majority of providers in the study reported that the single-item measures enhanced their practice and did not change the length of clinic visits. The authors concluded that the study showed that single-item PROs measures can be used in oncology clinics with positive implications for patients and physicians.

This study has several limitations. First, although the LASA and PRO-CTCAE questionnaires were collected prospectively in an institutional registry, there was decreasing questionnaire responses over time. Part of this is likely due to patients being lost to follow-up and due to the extra burden of filling our questionnaires. Furthermore, additional follow-up is needed to evaluate how PROs evolve over time. The study is also subject to selection bias as to which patient filled out the questionnaires in follow up. It is possible that patients were more likely to fill out the questionnaires if they experienced worse outcomes. Lastly, this study was performed at a single academic institution, thus limiting its applicability to other practices.

In conclusion, in patients treated with curative intent radiation for breast cancer, the single-item LASA scale correlated well with PRO-CTCAE and supports the assertion that single-item overall QOL LASA could be used as a screening tool for PROs. Patients who reported a worsening PRO-CTCAE item to ‘severe’ or worse experienced statistically significant and clinically meaningful deterioration in overall QOL based on LASA. Hypofractionation appears to improve overall QOL while higher BMI predicted for worse QOL. These results contribute to the understanding of PRO-CTCAE for breast cancer patients and promote the value of integration of PRO-CTCAE items into future clinical trials.

**Abbreviations**

AE: Adverse event; BC: Breast cancer; BIC: Bayes’ information criteria; BMI: Body mass index; FACT-Br: Functional Assessment of Cancer Therapy-Brain; LASA: Linear Analogue Self-Assessment; POMS-SF: Profile of Mood States-Short form; PRO-CTCAE: Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events; PRO: Patient-reported outcome; QOL: Quality-of-life; RT: Radiation therapy; SDS: Symptoms Distress Scale; UVA: Univariate.

**Previous presentations**

Presented in part at ASTRO 2020.

**Authors’ contributions**

CST was responsible for conception and design of the study, analysis and interpretation of the data, revisions, and a major contributor in writing the manuscript. TAD was responsible for conception and design of the study, and analysis of the data, and substantial revisions. MAG was responsible for design of the study and analysis of the data. RSB was responsible for conception and design of the study, and interpretation of the data. TZV, LAM, WWW, MYH,
and SRK were responsible for acquisition of the data and revisions. CEV was responsible for conception and design of the study, analysis interpretation of the data, revisions, and a major editing the manuscript. All authors approved and read the final manuscript.

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Availability of data and materials
We have full control over the primary data and will allow it to be reviewed if requested.

Declarations

Ethics approval and consent to participate
This study was approved by Mayo Clinic Institutional Review Board, IRB ID 19-000891.

Consent for publication
Informed consent was obtained from each patient to be included on the institutional prospective registry.

Competing interests
The authors declare that they have no competing interests.

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