

Clinical Investigation

# Low Interrater Reliability in Grading of Rectal Bleeding Using National Cancer Institute Common Toxicity Criteria and Radiation Therapy Oncology Group Toxicity Scales: A Survey of Radiation Oncologists



Minh-Phuong Huynh-Le, BS,\* Zhe Zhang, MS,<sup>†</sup>  
Phuoc T. Tran, MD, PhD,\* Theodore L. DeWeese, MD,\*  
and Daniel Y. Song, MD\*

Departments of \*Radiation Oncology and Molecular Radiation Sciences and <sup>†</sup>Oncology Biostatistics, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University School of Medicine, Baltimore, Maryland

Received May 21, 2014, and in revised form Aug 10, 2014. Accepted for publication Aug 13, 2014.

## Summary

A survey of genitourinary radiation oncologists was conducted to assess the NCI CTC and RTOG late toxicity scales for rectal bleeding after prostate radiation therapy. Participants graded toxicity in 4 patient cases using both scales (scales were provided for reference). Wide heterogeneities were observed among the participants grading rectal bleeding using 2 common scales. Clearer definitions for

**Purpose:** To measure concordance among genitourinary radiation oncologists in using the National Cancer Institute Common Toxicity Criteria (NCI CTC) and Radiation Therapy Oncology Group (RTOG) grading scales to grade rectal bleeding.

**Methods and Materials:** From June 2013 to January 2014, a Web-based survey was sent to 250 American and Canadian academic radiation oncologists who treat prostate cancer. Participants were provided 4 case vignettes in which patients received radiation therapy and developed rectal bleeding and were asked for management plans and to rate the bleeding according to NCI CTC v.4 and RTOG late toxicity grading (scales provided). In 2 cases, participants were also asked whether they would send the patient for colonoscopy. A multilevel, random intercept modeling approach was used to assess sources of variation (case, respondent) in toxicity grading to calculate the intraclass correlation coefficient (ICC). Agreement on a dichotomous grading scale (low grades 1-2 vs high grades 3-4) was also assessed, using the  $\kappa$  statistic for multiple respondents.

**Results:** Seventy-two radiation oncologists (28%) completed the survey. Forty-seven (65%) reported having either written or been principal investigator on a study using these scales. Agreement between respondents was moderate (ICC 0.52, 95% confidence

Reprint requests to: Daniel Y. Song, MD, Department of Radiation Oncology and Molecular Radiation Sciences, Sidney Kimmel Comprehensive Cancer Center, 401 N Broadway, Suite 1440, Baltimore, MD 21287. Tel: (410) 955-7019; E-mail: [dsong2@jhmi.edu](mailto:dsong2@jhmi.edu)

Conflict of interest: none.

Supplementary material for this article can be found at [www.redjournal.org](http://www.redjournal.org).

**Acknowledgments**—The authors thank the survey respondents for their participation, Drs Claire Snyder and Deborah Frassica for their feedback in survey development, and Ms Joyce Schanne for her assistance with survey and gift card distribution.

toxicity grading should be constructed to reduce this variability for both toxicity reporting and interpretation.

interval [CI] 0.47-0.58) when using NCI CTC and fair using the RTOG scale (ICC 0.28, 95% CI 0.20-0.40). Respondents who chose an invasive management were more likely to select a higher toxicity grade ( $P < .0001$ ). Using the dichotomous scale, we observed moderate agreement ( $\kappa = 0.42$ , 95% CI 0.40-0.44) with the NCI CTC scale, but only slight agreement with the RTOG scale ( $\kappa = 0.19$ , 95% CI 0.17-0.21).

**Conclusion:** Low interrater reliability was observed among radiation oncologists grading rectal bleeding using 2 common scales. Clearer definitions of late rectal bleeding toxicity should be constructed to reduce this variability and avoid ambiguity in both reporting and interpretation. © 2014 Elsevier Inc.

## Introduction

Radiation therapy (RT) is widely used today as a curative treatment modality for a number of cancers, including prostate cancer. Despite numerous advances in radiation technology and treatment planning methods, patients still experience acute and late sequelae of RT. These adverse effects are of equal importance as tumor control in the assessment of RT efficacy (1). Rectal bleeding is one of the most common late effects observed after prostate RT and is considered a dose-limiting toxicity.

Today, radiation oncologists frequently use toxicity scales from the National Cancer Institute (NCI) and the Radiation Therapy Oncology Group (RTOG) to report adverse outcomes after prostate RT. First developed in the early 1980s, the NCI Common Terminology Criteria for Adverse Events (CTCAE) is widely used as a classification and severity grading scale for adverse events in cancer clinical trials (2, 3). Version 4 is the most up-to-date edition of the CTCAE and was first released in May 2009. The RTOG and European Organization for Research and Treatment of Cancer (EORTC) have a morbidity scoring schema that covers the majority of organs and tissues in the body that may develop late radiation effects (4, 5). Variants of the RTOG grading scale have been in use since the 1970s. The NCI Common Toxicity Criteria (CTC) and RTOG scales both rely on user interpretation of patients' toxicity.

Despite the long use of these well-established scales, interobserver differences may exist in the interpretation of the toxicity scoring, but these have not been formally measured to date. In this study we conducted a survey to elucidate how genitourinary radiation oncologists rate (using the NCI CTC and RTOG scales) and manage rectal bleeding after RT.

## Methods and Materials

### Participants and procedures

Approval was received from the Johns Hopkins University Institutional Review Board for this study. Potential subjects were identified from American and Canadian academic radiation oncology Web sites, as well from an online

registry of clinical studies ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)), using search terms for prostate cancer RT (6). Subjects were considered eligible for this study if they were American or Canadian radiation oncologists within an academic setting who manage prostate cancer as a part of their routine clinical practice, and participants confirmed this within the questionnaire.

From June 2013 to January 2014, a Web-based survey (created using [www.surveymonkey.com](http://www.surveymonkey.com)) was sent to 250 American and Canadian academic radiation oncologists who treat prostate cancer. One reminder e-mail was sent within 2-4 weeks if subjects did not initially respond. Subjects were offered a \$50 gift card (choice of [Amazon.com](http://Amazon.com) or Starbucks) upon their completion of the survey and were entered into a drawing for \$199 toward the purchase of a tablet e-reader/browser.

### Study questionnaire

Participants were given 4 case vignettes in which patients with prostate cancer developed rectal bleeding within approximately 1 year after completion of RT (see [Appendix e1](#); available online at [www.redjournal.com](http://www.redjournal.com), for the full survey). Three cases involved patients treated with IMRT, and 1 case was for a patient treated with brachytherapy. Vignettes were based on actual cases observed and selected to represent a spectrum of what is encountered in clinical practice. The survey format and questions were developed and revised with input from four radiation oncologists at our institution with regard to clarity and overall representativeness of clinical practice. Management options were included on the basis of this feedback, as well as a literature search in [PubMed.com](http://PubMed.com) (terms: "rectal bleeding," "management," and "radiotherapy"). Participants were asked to rate the rectal bleeding according to NCI CTC v.4 and RTOG late toxicity grading using provided scales ([Table 1](#)). Both the NCI CTC and RTOG scales report toxicity on a 1-4 scale, with grade 1 being the mildest and grade 4 being the most severe (7, 8). In 2 cases, participants were asked whether they would send the patient for colonoscopy; if yes, they were provided results and asked for a management plan. Management options included invasive procedures (argon plasma coagulation, formalin application, electrocautery), patient self-administered procedures (eg, sucralfate, hydrocortisone, stool softeners, aminosaliclates), hyperbaric oxygen, and

Download English Version:

<https://daneshyari.com/en/article/8217938>

Download Persian Version:

<https://daneshyari.com/article/8217938>

[Daneshyari.com](https://daneshyari.com)