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Impact of Radiation Therapy on Aggressive Care and Quality of Life near Death

David Li, MD, PhD[1], **Holly G. Prigerson, PhD**[2,3], **Josephine Kang, MD, PhD**[4], and **Paul K. Maciejewski, PhD**[1,3]

[1]Department of Radiology, Weill Cornell Medical College, New York, NY, USA

[2]Department of Medicine, Weill Cornell Medical College, New York, NY, USA

[3]Center for Research on End-of-Life Care, Weill Cornell Medical College, New York, NY, USA

[4]Department of Radiation Oncology, Weill Cornell Medical College, New York, NY, USA

Abstract

Context—Radiation therapy (RT) is used with palliative intent in patients with advanced stage cancer. Prior studies, primarily in patients with poor performance status (PS), suggest that RT is associated with aggressive medical care, which may impact patients' quality of life near death (QoD) adversely.

Objective—This study examines associations between RT use and patients' receipt of aggressive care and QoD based on patients' PS.

Methods—Multi-institutional, prospective cohort study of patients with end-stage cancers (N=312) and identified as terminally ill at study enrollment. RT use (n=24; 7.7%) and Eastern Cooperative Oncology Group (ECOG) PS were assessed at study entry (median = 3.8 months before death). Aggressive care near death was operationalized as use of mechanical ventilation and/or resuscitation in the last week of life. QoD was determined using validated caregiver ratings of patients' physical and mental distress in their final week.

Results—RT use was associated with higher QoD (8/8, 100.0%, versus 58/114, 50.9%; p=0.006) among patients with good PS (ECOG=1), more aggressive care near death (3/9, 33.3%, versus 6/107, 5.6%; p=0.020) among patients with moderate PS (ECOG=2), and lower QoD (1/7, 14.3%, versus 28/51, 54.9%; p=0.046) among patients with poor PS (ECOG=3).

Corresponding Author: Paul K. Maciejewski, PhD, Center for Research on End-of-Life Care, Weill Cornell Medical College, 525 East 68th Street, Box 39, New York City, NY 10065, pam2056@med.cornell.edu, Phone: 212-746-1147, Fax: 212-746-4189.

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Conclusions—Targeted use of RT in end-of-life cancer care may benefit patients with good PS, but its use may adversely affect patients with poorer PS. Decisions about RT use in this setting should consider likely end-of-life outcomes based on patients' current PS.

INTRODUCTION

Radiation therapy (RT) has been one of the three pillars of cancer therapy, along with chemotherapy and surgery. It has been estimated that as much as 50% of the time RT is used to palliate patients with advanced cancer.[1] Common indications for palliative RT include treatment of brain metastases, airway obstruction, superior vena cava syndrome, spinal cord and/or nerve root impingement/compression, and alleviation of pain from bone and soft tissue metastases.[2] Consensus statements from the American Society for Therapeutic Radiation Oncology (ASTRO) summarize numerous trials demonstrating the safe, effective relief of cancer symptoms from palliative RT. [3,4,5]

Despite the role of RT in symptom management of patients with advanced cancer, evidence to guide its use in end-of-life cancer care is lacking. ASTRO consensus statements on palliative RT offer limited guidance on which patients are optimal candidates for treatment. [3,4,5] Among the three available statements, which address treatment of lung cancer and brain and osseous metastases, only the statement on brain metastases introduces criteria, based upon prognosis, for identifying patients suitable for RT. A single randomized study comparing RT to best supportive care for patients with poor prognosis (life expectancy < 3 months) was referenced in this report, and its results have yet to be published.[5]

Multiple randomized controlled trials have demonstrated the value of early palliative care intervention in patients with metastatic cancer, with improvements in both quality of life and survival.[6,7,8,9,10] Thus, targeted administration of RT might be expected to benefit some advanced cancer patients. However, population studies evaluating RT use near death suggest trends towards aggressive medical care,[1,11,12] casting doubt on the value of RT in this context. In a cohort of patients who died within 30 days of receiving palliative RT (median ECOG = 3), Gripp et al. found that half of patients spent > 60% of their remaining lifespan on treatment, with over half (51.6%) demonstrating no symptomatic benefit.[1] Through analysis of SEER-Medicare data, Guadagnolo et al. found that 17.8% of patients who received RT in their final 30 days of life spent more than 10 of those days receiving treatment.[12] These studies bring into question the value of prolonged courses of RT in end-of-life cancer care.

The aim of this study is to evaluate associations between RT use and patients' receipt of aggressive care near death, and patients' quality of life near death (QoD), based on patients' performance status (PS). We hypothesize that RT use in patients with good PS will be associated with higher QoD, and that RT use in patients with poor PS will be associated with aggressive care near death and lower QoD.

METHODS AND MATERIALS

Sample

Patients (N=312) were participants in a federally-funded, prospective, multi-institutional cohort study of advanced cancer patients and their caregivers. Participants were recruited between September 2002 and February 2008 from Yale Cancer Center (New Haven, CT), Veterans Affairs (VA) Connecticut Healthcare System Comprehensive Cancer Clinics (West Haven, CT), Parkland Hospital (Dallas, TX), Simmons Comprehensive Cancer Center (Dallas, TX), Dana-Farber Cancer Institute (Boston, MA), and New Hampshire Oncology-Hematology (Hookset, NH). Eligibility criteria required patients to have a diagnosis of advanced cancer (distant metastases; disease refractory to one or more lines of cytotoxic chemotherapy), a physician-formulated life-expectancy of six months or less, and adequate stamina to complete a baseline interview. Patients who met criteria for serious cognitive impairment[13] were excluded. Participants received $25 per interview for study participation. Review boards of all participating institutions approved study procedures; all participants provided written informed consent.

Of the 939 eligible patients, 661 (70.4%) participated. Reasons for nonparticipation were “not interested” (n=106), “caregiver refuses” (n=32), and “too upset” (n=21). Participants were more likely than non-participants to be Hispanic (78/661, 11.8% versus 17/252, 6.7%; p=0.025), but otherwise did not differ in socio-demographic characteristics. A majority of patient participants (384/661, 58.1%) died during the study observation period. Patients who died were more likely to be younger, non-white, unmarried, uninsured, less educated, and have had worse PS at study entry (all $p<0.05$) than patients who survived (277/661, 41.9%).

The cohort for the present analysis consisted of 312 terminally ill cancer patients, not participating in a clinical trial, who died within the study observation period. Among the 384 patients who died, 33 (8.6%) patients were excluded due to clinical trial participation. Among the remaining 351 patients who died, 39 (11.1%) were excluded due to missing data for PS or RT use at study entry or post-mortem assessment of QoD. Patients excluded due to missing data did not differ from patients included in the present sample either socio-demographically in terms of age, gender, race/ethnicity, marital status, and years of education, or clinically in terms of study entry PS and RT use.

Measures

Socio-demographic and baseline health status characteristics—Patients’ age, gender, race/ethnicity, years of education, marital status, and health insurance status were reported by patients during interviews conducted near time of enrollment (baseline). Disease information and cytotoxic chemotherapy use at baseline was obtained from medical charts. Information about the number and severity of the patient’s co-morbid illnesses at baseline was captured in the patient’s Charlson Comorbidity Index (CCI).[14]

Baseline Performance Status (PS)—Each patient’s functional status at study entry was evaluated by the treating oncologist using ECOG[15] PS: ECOG 0 = Fully active, able to carry on all pre-disease performance without restriction; ECOG 1 = Restricted in physically

strenuous activity but ambulatory and able to carry out work of a light or sedentary nature; ECOG 2 = Ambulatory and capable of all self-care but unable to carry out any work activities, up and about more than 50% of waking hours; ECOG 3 = Capable of only limited self-care, confined to bed or chair more than 50% of waking hours; ECOG 4 = Completely disabled, cannot carry on any self-care, totally confined to bed or chair. Patients' baseline ECOG and CCI were modestly correlated (r=0.18, p=0.002) in the present sample.

Baseline Radiation Therapy Use—Baseline RT use was defined in terms of whether or not the patient was in the process of receiving RT at time of enrollment, and represents a snapshot of patient RT use at that time, as determined by medical chart review. Number and duration of prior and subsequent treatments were not recorded. Evaluation of RT use at time of study enrollment irrespective of subsequent RT treatments allowed us to examine the potential influence of treatment decisions made relatively early in the process of end-of-life cancer care on aggressive care and quality of life near death.

Aggressive medical care near death—As in prior reports,[16,17] patient's receipt of aggressive care near death was operationalized as use of mechanical ventilation and/or resuscitation (VoR) in the last week of life. Within 2–3 weeks of the patient's death, the formal or informal caregiver most involved in the patient's last week of life provided information regarding the patient's care near death. Additional information on healthcare received in the last week of life was obtained from the patient's medical chart. As an indicator of aggressive care near death, VoR was positively associated with patient death in an intensive care unit (r=0.64, p<0.001) and negatively associated with hospice utilization near the end of life (r=−0.33, p<0.001) in the present sample.

Quality of Life near Death (QoD)—In a post-mortem interview conducted a median of 2.4 weeks after the patient's death, the formal or informal caregiver most knowledgeable of the healthcare the patient received in his/her final week was asked the following questions regarding the patient's quality of life at the end of life: "Just prior to the death of the patient (his/her last week, or when you last saw the patient), how would you rate his/her level of… " "psychological distress?" (0–10, 0 = none and 10 = extremely upset); "physical distress?" (0–10, 0 = none and 10 = extremely distressed); "overall quality of life in the last week of life/death?" (0–10, 0 = worst possible and 10 = best possible). Consistent with prior validation studies, we combined these three questions to assess patients' QoD,[18,19, 20] after reverse-coding the psychological and physical distress items. Composite scores were dichotomized, based on a median split, to reflect higher (158/312, 50.6%) and lower (154/312, 49.4%) patient QoD in the present analysis.

Statistical Analysis

Means, standard deviations, and frequencies were used to describe study variables. Bivariate associations between patient socio-demographic and clinical characteristics and baseline RT use were assessed using t-tests for continuous variables and chi-square tests for categorical variables. A Cox proportional hazards model was fit to determine if baseline RT use was associated with patient survival, defined as time from the patient's baseline interview until

the patient's death, adjusting for potential confounders (i.e., patient's site of enrollment and baseline PS).

Multiple logistic regression analysis tested the hypothesis that baseline PS modifies an association between baseline RT use and QoD. Patient QoD was regressed on the main and interactive effects of baseline RT use and PS. None of the examined patient socio-demographic and clinical characteristics were significantly associated with either patient baseline RT use or QoD, and therefore none of these were considered to be confounders in this analysis. Associations between baseline RT use and aggressive care near death and QoD, in an analysis stratified by baseline PS, were assessed in terms of 2×2 table probabilities using Fisher's Exact Tests. Statistical analyses were performed using SAS version 9.4 (SAS Institute Inc., Cary, NC); two-sided tests with $p<0.05$ were considered to be statistically significant.

RESULTS

Patients in the study cohort died a median of 3.8 months after their baseline interviews. At baseline, 2.9% (9/312) of patients were fully active (ECOG=0), 39.1% (122/312) were restricted but ambulatory and able to carry out light work (ECOG=1), 37.2% (116/312) were ambulatory and capable of all self-care but unable to carry out any work activities (ECOG=2), 18.6% (58/312) were capable of limited self-care and confined more than 50% of waking hours (ECOG=3), and 2.2% (7/312) were completely disabled (ECOG=4). At baseline, 7.7% (24/312) of patients were receiving RT. Based on post-mortem assessments, 7.7% (24/311) of patients received aggressive care near death.

Table 1 presents patients' characteristics and their associations with patients' baseline RT use. Majorities of patients were male (54.8%); white (61.5%); married (52.8%); and insured (54.5%). At study entry, considerably more patients were receiving cytotoxic chemotherapy (50.6%) as compared to RT (7.7%). There were no statistically significant differences in any of these patient characteristics, including baseline ECOG PS score, between the groups receiving and not receiving RT at study entry.

Based on results from a Cox proportional hazards model, patients' survival was not significantly associated with patients' baseline RT use, adjusting for patients' site of enrollment (i.e., academic medical center, hospital, or community clinic) and baseline PS score (AHR=0.95, $p=0.796$). Higher baseline ECOG score, i.e., poorer PS, was a significant mortality risk (AHR=1.54, $p<0.001$).

Based on results from a multiple logistic regression model that included the main and interactive effects of patients' baseline PS score and RT use on patients' QoD, patients' baseline PS score modified the effect baseline RT use on patients' QoD (interaction OR= 0.06, $p=0.009$). This significant modification of the effect of RT use on patients' QoD, as evidence that the effect of RT use on patients' QoD is dependent on patients' baseline PS, motivated an analysis of associations between baseline RT use and end-of-life outcomes stratified by patients' baseline PS.

Table 2a displays associations between patients' baseline RT use and aggressive care near death stratified by patients' baseline PS. RT use among patients with moderate PS (ECOG = 2) was associated with more aggressive care near death (3/9, 33.3%, versus 6/107, 5.6%; p=0.020). Table 2b displays associations between patients' baseline RT use and QoD stratified by patients' baseline PS. RT use among patients with good PS (ECOG = 1) was associated with higher QoD (8/8, 100.0%, versus 58/114, 50.9%; p=0.006). RT use among patients with poor PS (ECOG = 3) was associated with lower QoD (1/7, 14.3%, versus 28/51, 54.9%; p=0.046).

DISCUSSION

In the present study, we found no association between baseline PS and RT use. Nevertheless, we found PS to be an important factor in determining the impact of RT use on end-of-life outcomes. In our analysis stratified by patients' baseline PS, baseline RT use was associated with higher QoD among patients with good PS (ECOG = 1). In contrast, baseline RT use among patients with poorer PS (ECOG = 2 or 3) was associated with more aggressive care near death (ECOG = 2) or lower QoD (ECOG = 3).

Our studied cohort consisted of patients with physician-formulated life expectancies of less than 6 months, and who died within the study period. Thus, the observed associations between RT use and aggressive care near death and QoD, stratified by PS, are irrespective of prognosis. This suggests that a patient's current PS, as opposed to prognosis, is a better guide for deciding about RT use in end-of-life cancer care. Decisions about palliative RT on the basis of prognosis are limited by difficulties in making accurate prognostic estimates. In a cohort of patients who received RT within 1 month of death evaluated by Gripp et al., only 16% of patients were correctly estimated to have life expectancy < 1 month.[1] Krishnan et al. studied 862 patients who received palliative RT to identify better predictors of life-expectancy.[21] ECOG PS (2–4 versus 0–1) was one of several significant predictors of poor prognosis in their study (life-expectancy < 3 months). In the present cohort, we found beneficial effects of RT for patients with good PS regardless of the accuracy of their prognoses. ECOG PS is an easier and more reliable metric to determine as compared to prognosis. Thus, our study highlights its potential utility in identifying patients for appropriate RT use in end-of-life care.

In the present sample of advanced cancer patients, RT use was infrequent (7.7%) as compared to cytotoxic chemotherapy use (50.6%). The rate of RT use that we observed in this context is within the range of values reported in previously published studies.[12,22,23,24] In a study of SEER-Medicare data, Guadagnolo et al. reported that 8% of patients received RT in the last month of life.[12] Huang et al. [22] report rates of RT use of 22%, 5%, and 2% in the final year, 30 days, and 14 days of life, respectively. The rate of RT use in the present study, observed a median of 3.8 months before death, is closer to the value that Huang et al. report for the last 30 days of life than is it to the value they report for the last year of life. Patel et al. evaluated all patients who received RT over a period of one year at two tertiary care facilities and found that 6% of all patients received RT within a month of death.[23] Kapadia et al. found 10% of patients received RT in the last 14 days of life in a cohort of advanced non-small cell lung cancer patients treated at tertiary care centers.[24] Predictors of

receiving RT in the last 14 days of life included age < 65 at diagnosis, multi-organ involvement or stage IV disease at diagnosis, and treating institution. ECOG PS was found not to be a predictor of RT use,[24] consistent with our present findings.

Two national surveys, one involving ASTRO, the American Academy of Hospice and Palliative Medicine (AAHPM) and ASCO,[25] the other involving ASTRO and National Hospice and Palliative Care Organization (NHPCO),[26] investigated barriers towards integrating RT with palliative care. Most respondents felt RT was an important aspect of palliative care; however, multiple barriers including insufficient training between specialties and poor reimbursement limit appropriate use of RT in end-of-life care. In the present study, 15% and 65% of patients utilized inpatient and outpatient hospice services, respectively, near the end of life. Nevertheless, many hospice programs are unable to pay for palliative RT. In light of our present finding that RT use among patients with good PS is associated with better QoD, and the infrequent use and barriers to use of RT in end-of-life care, patients near the end of life with good PS would likely benefit from greater integration of RT with palliative care.

Wright et al., in a closely related cohort of terminally ill cancer patients from the parent study of the present study, found an association between cytotoxic chemotherapy use and aggressive care near death independent of baseline PS.[27] We demonstrate a similar association between RT and aggressive care near death, but only for patients with moderate PS (ECOG = 2). Mechanisms driving associations between cytotoxic chemotherapy and RT and aggressive care near death, and their differences based on patients' PS, are not well-understood and are important areas for future investigation. Consistent with our present finding, Kress et al. found in a population-based study that RT use within 6 months of death was associated with more emergency department visits, radiologic examinations, and physician visits.[28]

In 2012, an American Society of Clinical Oncology (ASCO) expert panel identified chemotherapy use among patients for whom there was no evidence of clinical value as the top most widespread, wasteful, and unnecessary practice in oncology.[29] Chemotherapy administration in the last two weeks of life is a benchmark for healthcare overuse; having associations with increased emergency room visits, intensive care unit admissions, hospital admissions, and in-hospital deaths.[30,31,32] The panel identified patient PS as a key indicator of when chemotherapy use is unlikely to have clinical value. Specifically, ASCO guidelines recommend against use of chemotherapy in solid tumor cancer patients who have not benefited from prior treatment and who have an ECOG PS ≥ 3. Our present results suggest that PS is also a key indicator of when RT use is unlikely to have clinical value. In light of the ASCO guidelines and the negative impact of RT on QoD for patients with poor PS (ECOG=3) reported here, discontinuation of both cytotoxic chemotherapy and RT should be deliberated for patients with poor PS (ECOG ≥ 3).

Recently, Prigerson et al., using these same data, demonstrated that cytotoxic chemotherapy use did not benefit end-stage cancer patients regardless of PS, and was associated with a detrimental effect on QoD in patients with good PS (ECOG = 1).[20] Our current findings expand upon Prigerson et al.'s results: RT use is positively associated, as compared to

cytotoxic chemotherapy use which is negatively associated, with better QoD in patients with good PS (ECOG =1). The mechanisms underlying this dramatic difference in effects of cytotoxic chemotherapy and RT on QoD for advanced cancer patients with good PS are not understood and merit future investigation. Nevertheless, our present findings support the use of palliative RT in advanced cancer patients with good PS.

Results of the present study, particularly as they relate to benefits or risks of palliative RT, should be interpreted with some caution. Limitations of this study include lack of detailed clinical information regarding RT technique, indication, dosage and fractionation, and about symptom relief and reductions in narcotic or steroid administration associated with RT. The present study is also limited in that it considers only a “snapshot” of RT use at time of study enrollment, a median of 3.8 months prior to patients’ deaths. When feasible, optimal palliative RT courses should be designed to minimize the time and cost burden of daily treatments to patients with limited life expectancy.[33] In a study of 1,574 patients with metastatic non-small cell lung cancer receiving palliative RT, many patients may have received a greater number of treatments and higher doses than what is supported by current evidence.[34] The small number of patients who received RT (n=24) is another limitation of the present study. The negative (i.e., non-significant) statistical tests that we report here are inconclusive due to the limited power of those tests, and indicate that larger, future studies might reexamine those hypotheses. Given the observational nature of the present study, it is possible that some unexamined factor may be a confounder in the present analysis. Further research is warranted regarding QoD, including use of more comprehensive measures of QoD (e.g., the Quality of Dying and Death questionnaire[35]), and optimal RT regimens for patients with good PS. Additional research is needed, using samples that include greater numbers of advanced cancer patients receiving RT, to determine factors that influence RT use near the end of life and to confirm the present findings.

RT use may contribute to higher patient QoD among relapsed metastatic cancer patients with good PS. However, RT use may lead to more aggressive care near death and lower patient QoD among patients with moderate and poor PS, respectively. Clinical practice guidelines in patients with advanced cancers should consider RT’s potential impact on end-of-life outcomes in light of patients’ current PS.

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Table 1

Associations between patient characteristics and baseline radiation therapy use (N=312)

Patient Characteristic	Full Sample (N=312)		Baseline Radiation Therapy Use				
			Yes (N=24)		No (N=288)		
Continuous	**mean**	**SD**	**mean**	**SD**	**mean**	**SD**	**p**
Age in years	58.6	12.6	61.0	14.1	58.4	12.5	0.333
Education in years	12.4	4.0	11.5	3.6	12.4	4.1	0.295
Charlson Comorbidity Index	8.6	2.6	8.8	2.5	8.6	2.6	0.667
Performance Status (ECOG) Score	1.8	0.9	2.0	0.8	1.8	0.9	0.295
Categorical	**n**	**%**	**n**	**%**	**n**	**%**	**p**
Gender, male	171	54.8%	14	58.3%	157	54.5%	0.718
Race/ethnicity							
White	192	61.5%	15	62.5%	177	61.5%	0.953
Black	64	20.5%	5	20.8%	59	20.5%	
Hispanic	52	16.7%	4	16.7%	48	16.7%	
Other	4	1.3%	0	0.0%	4	1.4%	
Married	162	52.8%	11	50.0%	151	53.0%	0.787
Health Insurance	165	54.5%	11	47.8%	154	55.0%	0.507
Recruitment Site							
Yale, Simmons, DFCI	90	28.8%	4	16.7%	86	29.9%	0.260
West Haven VA, Parkland	162	51.9%	13	54.2%	149	51.7%	
NH Oncology-Hematology	60	19.2%	7	29.2%	53	18.4%	
Cancer Diagnosis							
Lung	72	23.1%	9	37.5%	63	21.9%	0.219
Colon	40	12.8%	0	0.0%	40	13.9%	
Pancreatic	23	7.4%	1	4.2%	22	7.6%	
Other Gastrointestinal	38	12.2%	4	16.7%	34	11.8%	
Breast	42	13.5%	2	8.3%	40	13.9%	
Other	97	31.1%	8	33.3%	89	30.9%	
Cytotoxic Chemotherapy Use, Yes	158	50.6%	10	41.7%	148	51.4%	0.360

Variables missing data: Charlson (1), Married (5), Health Insurance (9)

Table 2a

Associations between baseline radiation therapy use and aggressive care (i.e., ventilation or resuscitation - VoR) near death in patients stratified by baseline performance status

Stratum			Baseline Radiation Therapy Use				
			Yes		No		
Performance Status (ECOG) Score	N	VoR	n	%	n	%	p
0 Asymptomatic	9	**Yes**	0		1	11.1%	n.e.
		No	0		8	88.9%	
1 Symptomatic, Ambulatory	121	**Yes**	0	0.0%	10	8.8%	0.491
		No	8	100.0%	103	91.2%	
2 Symptomatic, In Bed < 50% time	116	**Yes**	3	33.3%	6	5.6%	0.020
		No	6	66.7%	101	94.4%	
3 Symptomatic, In Bed > 50% time	58	**Yes**	0	0.0%	4	7.8%	0.589
		No	7	100.0%	47	92.2%	
4 100% Bedridden	7	**Yes**	0		0	0.0%	n.e.
		No	0		7	100.0%	

n.e. = not estimable

Table 2b

Associations between baseline radiation therapy use and higher quality of life near death (i.e., quality of death - QoD) in patients stratified by baseline performance status

Stratum			Baseline Radiation Therapy Use				
			Yes		No		
Performance Status (ECOG) Score	**N**	**QoD**	**n**	**%**	**n**	**%**	**p**
0 Asymptomatic	9	**High**	0		3	33.3%	n.e.
		Low	0		6	66.7%	
1 Symptomatic, Ambulatory	122	**High**	8	100.0%	58	50.9%	0.006
		Low	0	0.0%	56	49.1%	
2 Symptomatic, In Bed < 50% time	116	**High**	4	44.4%	52	48.6%	0.263
		Low	5	55.6%	55	51.4%	
3 Symptomatic, In Bed > 50% time	58	**High**	1	14.3%	28	54.9%	0.046
		Low	6	85.7%	23	45.1%	
4 100% Bedridden	7	**High**	0		4	57.1%	n.e,
		Low	0		3	42.9%	

n.e. = not estimable