International Journal of Radiation Oncology biology • physics

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Clinical Investigation

Quality Research in Radiation Oncology Analysis of Clinical Performance Measures in the Management of Gastric Cancer

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Received May 3, 2012, and in revised form Aug 14, 2012. Accepted for publication Aug 16, 2012

Summary

We report US national patterns of radiation therapy (RT) practice for non-metastatic gastric cancer treated from 2005 to 2007 inclusive, using a novel national process survey. Three clinical performance measures indicated widespread adoption of computed tomography-based treatment planning and use of DVHs to evaluate normal tissue doses and completion of adjuvant radiation in the prescribed time frame. Three emerging quality indicators

Background: The specific aim was to determine national patterns of radiation therapy (RT) practice in patients treated for stage IB-IV (nonmetastatic) gastric cancer (GC).

Methods and Materials: A national process survey of randomly selected US RT facilities was conducted which retrospectively assessed demographics, staging, geographic region, practice setting, and treatment by using on-site record review of eligible GC cases treated from 2005 to 2007. Three clinical performance measures (CPMs), *(1)* use of computed tomography (CT)-based treatment planning; *(2)* use of dose volume histograms (DVHs) to evaluate RT dose to the kidneys and liver; and *(3)* completion of RT within the prescribed time frame; and emerging quality indicators, *(i)* use of intensity modulated RT (IMRT); *(ii)* use of image-guided tools (IGRT) other than CT for RT target delineation; and *(iii)* use of preoperative RT, were assessed.

Results: CPMs were computed for 250 eligible patients at 45 institutions (median age, 62 years; 66% male; 60% Caucasian). Using 2000 American Joint Committee on Cancer criteria, 13% of patients were stage I, 29% were stage II, 32% were stage IIIA, 10% were stage IIIB, and 12% were stage IV. Most patients (43%) were treated at academic centers, 32% were treated at large nonacademic centers, and 25% were treated at small to medium sized facilities. Almost all patients (99.5%) underwent CT-based planning, and 75% had DVHs to evaluate normal tissue doses to the kidneys and liver. Seventy percent of patients completed RT within the prescribed time frame. IMRT and IGRT were used in 22% and 17% of patients, respectively. IGRT techniques included positron emission tomography (n = 20), magnetic resonance imaging (n = 1),

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Quality Research in Radiation Oncology is supported by National Institutes of Health National Cancer Institute grant CA065435.

Conflict of interest: none.

Supplementary material for this article can be found at www.redjournal.org.

http://dx.doi.org/10.1016/j.ijrobp.2012.08.021

demonstrated that intensity modulated RT, image guided RT, and neoadjuvant RT were not routinely incorporated into clinical practice during that time frame.

respiratory gating and 4-dimensional CT (n = 22), and on-board imaging (n = 10). Nineteen percent of patients received preoperative RT.

Conclusions: This analysis of radiation practice patterns for treating nonmetastatic GC indicates widespread adoption of CT-based planning with use of DVH to evaluate normal tissue doses. Most patients completed adjuvant RT in the prescribed time frame. IMRT and IGRT were not routinely incorporated into clinical practice during the 2005-2007 period. These data will be a benchmark for future Quality Research in Radiation Oncology GC surveys. © 2012 Elsevier Inc.

Introduction

Assessing quality of cancer care has become a national priority. There are wide variations in practice patterns and quality of care in the United States. The introduction of novel technologies and treatment paradigms for specific types of cancer have made it imperative that measures be developed to monitor the national quality of cancer care and to guide the use of new treatment approaches. Quality assessment and improvement in radiation oncology has been the focus of the American College of Radiology (ACR) through the Patterns of Care Studies (PCS) initiated in 1973 (1). PCS has helped to identify and monitor national standards of radiation oncology practice for multiple disease sites through national practice pattern surveys (2). Recently, the ACR introduced Quality Research in Radiation Oncology (QRRO), broadening the aims of the PCS to include developing clinical performance measures (CPMs) that may be used as quality indices. These CPMs can provide feedback to physicians by identifying areas for improvement in the adoption of evidence-based recommendations for radiation therapy (RT) use.

Gastric cancer was chosen in the QRRO process surveys to define nationwide patterns of care and to examine the penetration of clinical trial results on those practice patterns. Historically, RT has played a minor role in the treatment of gastric cancer. In 2001, MacDonald et al (3) reported Gastric Surgical Adjuvant Trial (INT-0116) results showing a clear survival advantage to the use of chemoradiation after resection for gastric cancer, supporting a major role for RT in the adjuvant treatment of this disease. That study established postoperative chemoradiation as a standard of care for patients with resected stage IB through IV (M0), gastric or gastroesophageal (GE) junction adenocarcinoma. While INT-0116 established postoperative chemoradiation as a validated standard-of-care treatment in North America, most practicing radiation oncologists have not been trained to treat gastric cancer patients in a potentially curative setting. Thus, the technique of RT used in the postoperative adjuvant treatment of gastric cancer has varied greatly. Suboptimal RT is associated with worse outcome (4). Therefore, the aim of the QRRO survey for gastric cancer treatment was to assess the quality of postoperative RT.

Over the past decade new technologies have been introduced into clinical practice, for example, intensity modulated RT (IMRT) and image guided RT (IGRT). The QRRO surveys also assessed use of advanced radiation treatment technology to establish a benchmark for its appropriate use in the management of gastric cancer.

Methods and Materials

Gastric cancer national process survey

A national process survey was developed for gastric cancer by the QRRO Gastrointestinal Committee to collect data on patient demographics, diagnosis, staging, history, geographic region, practice setting, insurance status, comorbidities, treatment (planned and delivered), and toxicities. The Gastric Cancer Process Survey (see supplementary Appendix EA) was conducted for patients treated from 2005 through 2007 at 45 institutions. A stratified 2-step cluster sampling method was used to select radiation oncology facilities from a master list of 1879 United States radiation oncology facilities. Before selection, facilities on the master list had been stratified by type as academic (the main teaching hospital of a medical school or National Cancer Institute-designated Comprehensive Cancer Center); large nonacademic (other facility with 3 or more linear accelerators actively treating patients); medium nonacademic (other facility with 2 linear accelerators actively treating patients); and small nonacademic (other facility with 1 linear accelerator actively treating patients). In all, 106 facilities were randomly selected by stratum and invited to participate in a survey of RT practices. Of these facilities, 45 (42%) participated in the study: 14 (of 25) were academic, 13 (of 27) were large nonacademic, 7 (of 27) were medium nonacademic, and 11 (of 27) were small nonacademic facilities.

In the second sampling stage, individual gastric cancer cases were randomly selected for review and data abstraction based on lists of all eligible patients provided by the treating facilities. QRRO randomly selected 10 eligible patients at each facility (or all eligible patients if fewer than the required number had been treated during the study period). Eligibility criteria included receipt of adjuvant or neoadjuvant RT for gastric cancer between 2005 and 2007, histologic diagnosis of adenocarcinoma, squamous cell carcinoma or adenosquamous carcinoma of the stomach or GE junction, American Joint Committee on Cancer (AJCC) 2002 stage Ib, II, III, or IV (nonmetastatic) disease, no evidence of distant metastases, Karnofsky performance status of $\geq$60%, and no malignancies within the previous 5 years. Facility and process survey data were collected through retrospective patient record review by ACR Clinical Data Abstractors.

Clinical performance measures

The QRRO Gastrointestinal Committee defined quality indicators that served as CPMs, including adherence to published national practice guidelines, appropriateness criteria, penetration of results of clinical trials, and integration of emerging and advanced technologies. The 3 core CPMs, developed to assess the adherence to current measure (CM) practice guidelines for RT in the management of gastric cancer, as follows.

CM IA

Use of computed tomography (CT)-based simulation and treatment planning.

CM IB
Use of dose volume histograms (DVH) to evaluate normal tissue doses to the kidneys and liver.

CM II
Completion of the planned RT course within the prescribed time frame (33-45 days).

Three additional quality indicators were developed as emerging measures (EM), based on best available evidence and expert consensus to assess the incorporation of emerging and advanced technologies and practices that have not been validated by clinical trials but may be integrated into practice as part of RT for gastric cancer, as follows.

EM IA
Use of IMRT treatment delivery when 3-dimensional (3D) conformal technology is used in treatment planning.

EM IB
Use of IGRT other than CT scans for RT target delineation and treatment delivery.

EM II
Use of preoperative (neoadjuvant) RT prior to a planned surgical resection (in contrast to initial surgery followed by adjuvant chemoradiation therapy).

Each CPM was then calculated to characterize the proportion of patients who met the criteria defined for that performance measure. Survey data corresponding to outcomes and techniques defined in the performance measures were used to measure compliance with these quality indicators or use of the indicated techniques.

Computation of CPM

The proportion of patients who met the defined criteria was calculated as CPM = [Subset of the patient population with the condition that meets the defined criteria]/[Patient population with the condition − Patients with exclusions].

Statistical analysis

Statistical analysis was conducted using SUDAAN statistical software (RTI International, Research Triangle Park, NC) (5), incorporating the design elements (the 2 stages of stratification) and weights that reflected the relative contribution of each institution and each patient in the analysis of this survey, providing estimates of national figures for patients meeting the survey eligibility requirements. Weights were calculated for each patient record based on the relative sample and population size of each institution and patient. Stratum-specific weighted percentages were calculated to reflect the distribution in the whole population. These percentages were used to estimate national averages from which statistically valid inferences could be drawn for national process measures.

National estimates were calculated from the survey data using SUDAAN statistical software (RTI International), incorporating the design elements and weights that reflected the relative contribution of each patient in the analysis of this complex survey (5). The weights for each case in a stratum were the product of the following 2 factors: [Estimated number of eligible cases in the population]/[Number of eligible cases in sample × Proportion of eligible cases in the population/Proportion of eligible cases in the sample].

Two SUDAAN procedures were used to analyze the data: one procedure for percentages and tests of categorical variables (PROC CROSSTAB) and the other procedure for descriptive statistics and tests of continuous variables (PROC DESCRIPT). Tests for association were performed using the Pearson χ^2 test in SAS, version 9.2 (English) for Windows, Cary, NC, and SUDAAN, version 10.0, Research Triangle Park, NC, (5, 6). Differences were deemed significant if the associated P values were $<.05$.

Although national estimates were computed using weights reflecting the relative contribution of each institution and each patient in the sample (Table 1 and 2), results comparing small subsets of patients are reported for the surveyed sample. Since the CPMs are computed for small subsets of patients, they are reported as unweighted case counts in each category (Table 3).

Results

Patient and facility characteristics

Charts of 250 patients treated for gastric cancer at 45 institutions met criteria for inclusion in this survey, representing a weighted national sample size of 9567 patients. Patient and tumor characteristics are listed in Table 1. The median age of patients treated was 63 years of age, and 65% were male. The racial distribution of patients was: 68% Caucasian, 17% African American, and 6% Asian, and 8% were other race or unknown. The majority (96%) of patients had a histologic diagnosis of adenocarcinoma. Primary tumor location was in the antrum in 35%, the corpus in 14%, the cardia in 12%, and the GE junction in 33%, according to the pathology report. Staging was based on AJCC 2002 pathologic staging system. Fourteen percent of patients had stage IB disease, 27% had stage II, 30% had stage IIIA, and 9% had stage IIIB, and 14% of patients were coded as having stage IV disease, presumably nonmetastatic, but with the primary tumor involving adjacent structures in the presence of involved nodes or those with N3 disease.

The largest proportion of patients (36%) was treated at small nonacademic centers, followed by medium (29%) and large (24%) nonacademic facilities, and only 11% of patients were treated at academic centers. Forty-nine percent of the patients were treated at radiation oncology facilities located in the southern United States, and the remainder was evenly split between treatment in northeastern (19%), midwestern (16%), and western (16%) United States. The primary payment method for the most patients (39%) was Medicare, while 29% had private insurance, and 13% were covered by a Health Maintenance Organization; only 4% had Medicaid as a primary payer.

Quality indices and CPMs

Data from specific survey items addressing the treatment course and particular treatment techniques as they applied to the performance measures were collected (Table 2).

The core CPMs demonstrated excellent adherence to national guidelines (Fig. 1) (7, 8). Almost all (99.6%) patients underwent CT-based planning, and 75% had DVHs to evaluate normal tissue doses to kidneys and livers. The median prescribed dose was 4493

Table 1 Patient and tumor characteristics

Characteristic	Weighted no. of patients* (n=9567)	% of patients*	Unweighted no. of patients (n=250)
Age at start of RT (y)			
Mean	62		
Median	63		
Range	33-94		
Sex			
Male	6187	64.7	166
Female	3380	35.3	84
Race			
White	6519	68.1	150
Black/ African American	1654	17.3	58
Asian	611	6.4	17
Other/unspecified	782	8.2	25
Ethnicity			
Hispanic	1370	14.3	30
Not Hispanic/ unspecified	8197	85.7	220
Marital status			
Married	6473	67.7	175
Single	2046	21.4	53
Not specified	1048	11.0	22
Primary payment method			
Medicare	3731	39.0	85
Private insurance	2811	29.4	85
Health Maintenance Organization	1231	12.9	29
Medicaid	365	3.8	14
Government insurance	699	7.3	19
Self-pay	374	3.9	11
Not specified	355	3.7	7
Stratum			
Academic	1074	11.2	108
Large nonacademic (>3 LINACS)	2259	23.6	79
Medium nonacademic (2 LINACS)	2763	28.9	30
Small nonacademic (1 LINAC)	3470	36.3	33
Census region			
Northeast	1774	18.5	43
Midwest	1546	16.2	59
South	4716	49.3	104
West	1531	16.0	44
Karnofsky performance status†			
60	249	2.6	4
70	823	8.6	18
80	2541	26.6	69
90	4499	47.0	122
100	1445	9.8	36
Stage			
IB	1314	13.7	33
II	2623	27.4	73
IIIA	2881	30.1	81
IIIB	879	9.2	25
IV	1293	13.5	29
Unknown	577	6.0	9
Histology			
Squamous cell	57	0.6	2
Adenocarcinoma	9203	96.2	242
Adenosquamous	277	2.9	5
Unknown	29	0.3	1
Primary location of tumor			
Antrum	3345	35.0	94
Corpus	1337	14.0	34
Cardia	1119	11.7	32
GE junction	3145	32.9	70
Unknown	621	6.5	20

Abbreviation: LINAC = linear accelerator.

* Percentages are based on the weighted number of patients and may not add up to 100 due to rounding errors.

† KPS was not recorded for 1 patient (weighted sample, n=10).

cGy, corresponding to the 4500-cGy dose prescribed in the INT-0116 trial. The median duration of RT was 36 days for patients who completed treatment. Seventy-one percent of patients completed RT within the prescribed time frame of 33 to 45 day, a quality indicator of appropriate treatment delivery.

For emerging quality indicators (Fig. 2), there was a lower frequency of the use of advanced technology. During this time period, IMRT was used for treatment planning in only 22% of patients. Most patients (46%) were treated with a 4-field plan, 20% were treated with >4 fields, 15% were treated with an anteroposterior-posteroanterior (AP-PA) field arrangement and 14% with a 3-field plan. There was a statistically significant difference ($P<.0001$) between the use of IMRT by academic centers compared with that by nonacademic centers, indicating increased use of emerging techniques in the academic centers (Table 3). Image guidance was used in only 18% of patients, with no statistical difference between facility types in regard to use of IGRT. IGRT techniques included positron emission tomography scans (n=20), magnetic resonance imaging (n=1), respiratory gating and/or 4D-CT (n=22), and on-board imaging (n=10). Among patients receiving RT as part of their management of gastric cancer, only a minority (19%) received it in the preoperative setting (EM II). Only 6% of patients were treated using a clinical protocol (Table 4).

Discussion

The QRRO gastric process survey was performed to evaluate the quality of RT in the management of gastric cancer over a time period during which both new guidelines for adjuvant RT were

Table 2 Treatment characteristics

Characteristic	Weighted no. of patients (n=9567)		Unweighted no. of patients (n=250)	
Total radiation dose (cGy)	No.	%‡	No.	%‡
All patients				
Mean	4554			4550
Median	4493			4500
Range	180-6640			180-6640
Patients who completed RT (n=8688)			n=223	
Mean	4679			4668
Median	4494			4500
Range	2000-6640			2000-6640
Patients who did not complete RT (n=879)			n=27	
Mean	3317			3568
Median	3234			4140
Range	180-5100			180-5100
Duration of RT (d)*				
All patients (n=9538)†			n=249†	
Mean	37.7			37.1
Median	36.2			36.0
Range	0-122			0-122
Patients who completed RT (n=8659)			n=222	
Mean	38.6			38.1
Median	36.4			36.0
Range	4-122			4-122
Patients who did not completed RT (n=879)			n=27	
Mean	28.6			29.1
Median	28.0			32.0
Range	0-53			0-53
Technique				
AP-PA	1409	14.7	48	19.2
3-field	1360	14.2	42	16.8
4-field	4390	45.9	87	34.8
>4-field	1895	19.8	64	25.6
Other/unknown	513	5.4	9	3.6
Investigational protocol				
None	8962	93.7	226	90.4
NCI Clinical Trials Cooperative Group	286	3.0	9	3.6
IRB-approved institutional clinical trial	242	2.5	11	4.4
IRB-approved PHARMA/device clinical trial	77	0.8	4	1.6

Abbreviations: IRB = institutional review board; NCI = National Cancer Institute; PHARMA = pharmaceutical company.

* Duration was computed as treatment end date minus treatment start date. Thus, if only one fraction was given, duration was computed as 0 d.

† Duration of RT was not recorded for 1 patient (weighted sample, n=29).

‡ Percentages are based on the weighted number of patients and may not add up to 100 due to rounding.

being adopted into clinical practice and new techniques were being introduced into the planning and delivery of RT for many tumor types. Adjuvant chemoradiation was shown in the INT-0116 trial to improve both disease-free and overall survival, presumably by sterilizing occult regional microscopic disease (3). This was a large phase 3, randomized trial of surgery alone versus surgery followed by fluorouracil/leucovorin and RT (45 Gy). These results led to the adoption of postoperative chemoradiation as the standard of care in the United States for resected gastric cancer patients. However, adjuvant RT for gastric cancer had not been incorporated routinely into the educational curriculum in radiation oncology training programs so that many radiation oncologists were not adequately trained to plan adjuvant gastric RT, as demonstrated in the quality of the RT fields on the INT-0116 trial. As a protocol requirement, RT plans were centrally reviewed as part of the quality assurance before initiating therapy. Of the initial radiation plans, 35% had major or minor deviations from the protocol treatment planning requirements. After the plans were sent back for replanning, 6.5% still had major deviations in a second review after RT delivery (4). Poor compliance with the protocol treatment planning recommendations may have reflected unfamiliarity with the postoperative abdominal anatomy but also may have been due to concerns about potential toxicity associated with large fields (4).

In order to address the variations in RT treatment planning for gastric cancer, a consensus report was published in February 2002 to address anatomic considerations in the postoperative abdomen after total or partial gastrectomy and to define areas at highest risk for harboring subclinical disease (9). Also, National Comprehensive Cancer Network (NCCN) guidelines incorporated further

Table 3 Clinical performance measures by type of facility

Clinical performance measure (Unweighted No. of patients and %)	Academic		Large nonacademic		Medium nonacademic		Small nonacademic		
	No.	%*	No.	%*	No.	%*	No.	%*	χ^2 *P*
CM IA: use of CT-based simulation and planning (N=249)†	107		79		30		33		
YES (n=249) 100.0%	107	100.0	79	100.0	30	100.0	33	100.0	§NA
CM IB: use of DVH to evaluate normal tissue dose to the kidneys and liver (N=249)†	107		79		30		33		
NO (n=62) 24.9%	14	13.1	30	38.0	13	43.3	5	15.2	
YES (n=187) 75.1%	93	86.9	49	62.0	17	56.7	28	84.9	<.0001
CM II: completion of planned RT course within the prescribed time frame of 33-45 d (N=191)	83		59		25		24		
NO (n=56) 29.3%	23	27.7	21	35.6	7	28.0	5	20.8	
YES (n=135) 70.7%	60	72.3	38	64.4	18	72.0	19	79.2	.5561
EM IA: use of IMRT for RT treatment delivery when 3D conformal technology is used in treatment planning (N=249)†	107		79		30		33		
NO (n=194) 77.9%	68	63.6	73	92.4	28	93.3	25	75.8	
YES (n=55) 22.1%	39	36.5	6	7.6	2	6.7	8	24.2	<.0001
EM IB: use of image-guided tools other than CT scans for RT target delineation (N=250)	108		79		30		33		
NO (n=206) 82.4%	85	78.7	69	87.3	24	80.0	28	84.9	
YES (n=44) 17.6%	23	21.3	10	12.7	6	20.0	5	15.2	.4569
EM II: use of preoperative (neoadjuvant) RT (N=201)‡	90		60		26		25		
NO (n=163) 81.1%	71	78.9	50	83.3	20	76.9	22	88.0	
YES (n=38) 18.9%	19	21.1	10	16.7	6	23.1	3	12.0	.6698

Abbreviations: CM = current measure; EM = emerging measure; NA = not applicable.

§ 50% of the cells have expected counts less than 5. The χ^2 test may not be valid.

* Percentages shown are column percents and may not add up to 100 due to rounding errors.

† Use of 3D conformal technology was unknown for 1 patient.

‡ Surgical resection was not planned for 35 patients and 14 patients were excluded for comorbidities.

recommendations in regard to RT techniques, dose, fractionation, and normal tissue constraints (7). Level I evidence from the randomized trial and published national guidelines were the bases for the quality indicators that were measured through the QRRO gastric cancer process survey.

The 3 core CPMs were based on accepted standard-of-care techniques that have been routinely integrated into RT practices. In particular, CT-based RT simulation and planning techniques have been shown to improve the precision of RT delivery in many cancers and the accuracy of delineating areas at risk in the abdomen for patients receiving adjuvant RT for gastric cancer while minimizing the volume of normal tissue irradiated. Dosimetric analyses of AP-PA versus CT-based 3D conformal RT (3DCRT) plans have shown reduced doses to the kidneys using 3DCRT (10). Clinical studies have demonstrated a decrement in renal function after adjuvant RT for gastric cancer, which may be reduced by using 3D treatment planning techniques (11). NCCN guidelines strongly encourage the use of CT simulation and 3D treatment planning (apparently universally practiced with 99.6% of patients reported herein) (7). There was also excellent adherence to the use of DVHs to evaluate normal tissue doses and to limit doses to the liver and kidneys based on the known radiation tolerance doses of these organs (75% of patients reported herein). Finally, completion of RT without prolonged treatment breaks has been associated with better clinical outcomes for several tumor sites, including head and neck, cervical, and anal canal carcinomas (12-14). Adjuvant chemoradiation therapy for gastric cancer can be associated with large radiation fields and significant acute toxicity (3). In the INT-0116 trial, completely resected gastric cancer patients received adjuvant radiation using AP-PA fields, and 41% of patients reported grade 3 or 4 toxicity, with

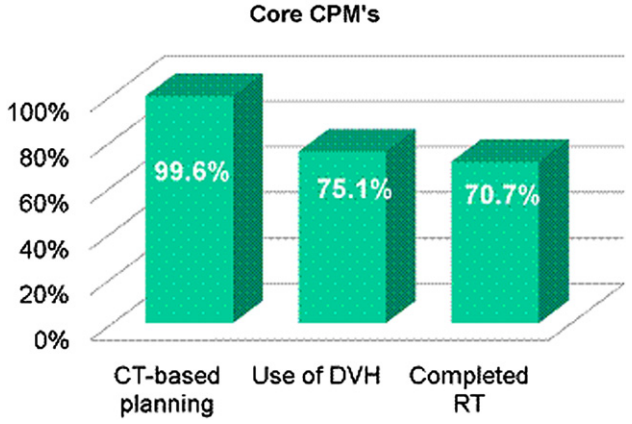

Fig. 1. Core CPMs of RT practice for gastric cancer.

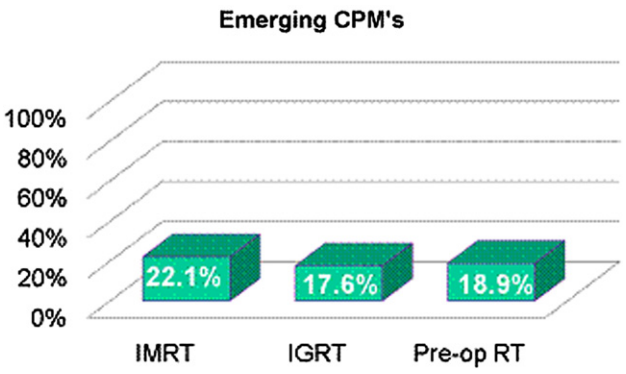

Fig. 2. Emerging CPMs to assess incorporation of newer RT techniques in the management of gastric cancer.

17% unable to complete the radiation protocol. With improved planning techniques using CT-based planning to spare normal tissue, fewer patients should require prolonged treatment breaks or discontinuation of RT (15). In the cohort of patients who received treatment using 3DCRT, over 70% were treated in a timely fashion, and only 9% did not complete therapy, an indicator that the quality of care is improving with the incorporation of better treatment techniques.

Another objective of the QRRO gastric process survey was to track the distribution and use of advanced RT technology with the goal of assessing the appropriate use of these emerging technologies. As radiation oncologists incorporate new technology into their practice, reassessment of quality of care is necessary to inform practitioners of their professional performance and to hold radiation oncologists accountable for the use, misuse, overuse, or under-use of advanced RT technology. While the findings from QRRO's analysis of radiation practice patterns for gastric cancer indicate widespread adoption of CT-based planning with the use of DVHs to evaluate normal tissue doses, only 22% and 18% of patients were treated with emerging RT techniques such as IMRT and IGRT, respectively. In addition, the last emerging CPM (EM II) assessed the use of preoperative RT in gastric cancer as it has become standard for many gastrointestinal malignancies, most notably for rectal cancer, where there is clearly a benefit to preoperative chemoradiation therapy for both toxicity and local control (16). This may also hold true for gastric cancers as the diverse and widespread patterns of direct extension and lymphatic drainage oblige the radiation oncologist to treat very large fields to cover areas of potential relapse (3, 9). Preoperative treatment facilitates tumor downstaging prior to resection and allows adjuvant treatment to be delivered when local tissue has been surgically undisturbed. Phase 2 data from the University of Texas MD Anderson Cancer Center have demonstrated excellent R0 resection rates with preoperative chemoradiation therapy for gastric cancer (17). Early results suggest promising preliminary outcomes and toxicity profiles. Pathology response rates following preoperative chemoradiation is predictive of overall survival in gastric cancer (18). Interestingly, the use of preoperative RT was used only in a minority (19%) of patients, implying that despite phase 2 data (17) evaluating the use of preoperative chemoradiation for gastric cancer, when RT is used in a nonprotocol setting for the management of nonmetastatic gastric cancer, it is being incorporated according to the guidelines outlined by the INT-0116 trial. These data on emerging quality indicators will serve as a benchmark for future QRRO gastric cancer surveys.

A limitation of this analysis is that the institution and gastric cancer case cohorts were not exhaustive, and, despite using weighting techniques to reflect the relative contribution of each institution and each patient, we assessed only 45 institutions. In addition, while there is an indication that academic centers may be using emerging techniques more than other centers, with this design, we cannot infer a definite causality link. Finally, further changes in practice patterns have occurred between the time of observation and this publication, for example, perioperative chemotherapy has become more commonly practiced since publication of the Medical Research Council Adjuvant Gastric Infusional Chemotherapy(MAGIC) Trial (19), and neoadjuvant chemoradiation may be used more often for GE junction cancers because they are being considered more closely related to esophageal cancer. Thus, recent practice changes may impact the applicability of these results. However, these data provide a validated measure of gastric cancer care in the United States that demonstrate relatively good compliance with national guidelines (7, 8).

Future Directions

As RT techniques become more complex, with integration of stereotactic approaches, on-board imaging, and motion management

Table 4 Emerging measure II by investigational protocol

Emerging measure	Not on any investigational protocol (Unweighted) No.	%*	On NCI clinical trials (Unweighted) No.	%	On IRB-approved inst/ PHARMA/ Device CT (Unweighted) No.	%*	Pearson χ^2 $P^{\dagger}$
EM II: use of preoperative (neoadjuvant) RT (n=201)[‡]	179	89.1	9	4.5	13	6.5	
NO (n=163)	150	92.0	7	4.3	6	3.7	
YES (n=38)	29	76.3	2	5.3	7	18.4	.0036

Abbreviations: CT = clinical trial; EM = emerging measure; inst = institutional; IRB = institutional review board; NCI = National Cancer Institute; PHARMA = pharmaceutical company.

* Percentages shown are row percents and may not add up to 100 due to rounding errors.

† A total of 33% of the cells had expected counts less than 5. The χ^2 test may not be valid.

‡ Surgical resection was not planned for 35 patients; 14 patients were excluded for comorbidities.

methods into daily practice, there will be an ongoing need for quality assurance. The QRRO is developing processes using Web-based platforms to download deidentified patient data, including imaging information, to a central site. Treatment quality can then be assessed in an almost real-time manner, allowing for more immediate feedback through comparisons of individual outcomes with quality measures defined for this particular treatment type. A pilot study to evaluate this approach has been performed for prostate brachytherapy and has demonstrated the feasibility of remote central review to assess the quality of implant procedures (20).

Advances in statistical methods and computing power have made comparative effectiveness research studies possible, using comprehensive detailed data extracted from electronic medical record systems. Clinically relevant alternative interventions can be analyzed in diverse populations from heterogeneous practice settings, leading to a broad range of health outcomes. A wide range of potentially confounding factors can be accounted for through rigorous study designs in naturalistic settings that can determine the generalizability of results from randomized controlled trials. QRRO will continue to play a critical role in maintaining the high quality of radiation oncology practice through expanding opportunities for self-assessment, setting standards for quality of care, and conducting rigorous studies of the outcomes of care.

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