A Survey of the ITC Volumetric Treatment Planning Data Archive Supporting RTOG Advanced Technology Clinical Trials

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Abstract

Purpose: Survey of volumetric treatment planning (TP) data, linked to outcomes, collected by the Image-guided Therapy QA Center (ITC) in 15 years of facilitating QA review for RTOG multi-institutional advanced technology (AT) clinical trials.

Materials & Methods: The ITC as part of the Advanced Technology QA Consortium (ATC) collects volumetric TP data sets linked to outcomes for RTOG Advanced Technology clinical trials. CT images, target-volume/organ-at-risk contours, and 3-D dose distributions exported from commercial TP systems are submitted to the ITC using either DICOM or RTOG Data Exchange format. ITC staff evaluates dataset integrity and completeness, and requests re-submission as needed. Dose-Volume Histograms (DVHs) for required volumes are recalculated from submitted contours and dose distributions. RTOG dosimetrists and study chairs review contours and dose distributions for protocol compliance using ITC's web-based Remote Review Tool (RRT). Clinical outcomes are reported to RTOG headquarters using protocol-specific forms.

Results: The ITC has collected over 5000 complete TP data sets quantifying the relationship between image-based anatomy and planned doses. Disease sites treated in the 10 closed protocols (1800 cases) include prostate, lung, brain, head/neck, and breast. An additional 13 active protocols (>3500 cases) also include liver, cervix, and anus. A sample of data sets available for analysis is listed below. (Doses (Gy) and % volumes are the minimum/maximum/average values.)

Prostate (3DCRT, N=984; PTV D98: 52.2/81.6/75.0, bladder Dmean: 4.9, 75.9, 37.7, rectum Dmean: 12.9, 72.5, 42.7, femoral heads Dmean: 1.8, 49.5, 32.4),

Head&Neck (IMRT, N=64 ; PTV D98: 58.0/73.4/67.6, spinal cord D2: 32.8/44.8/39.6, parotid Dmean: 21.2/50.3/32.4, larynx Dmean: 3.9/57.7/32.9),

Lung (3DCRT, N=158; PTV D98: 50.3/98.2/77.4, spinal cord D2: 0.1/60.1/26.0, esophagus Dmean: 0/63.8/15.9, heart Dmean: 0/45.3/10.5, liver Dmean: 0/19.3/1.2, brachial plexus Dmean: 0/57.7/4.6, lung V20: 5.3/46.6 /21.2 %,).

The ITC has provided access to these TP protocol data sets for secondary analysis by: (1) export of entire TP data sets as RTOG data exchange files and (2) online data analysis using the RRT. External investigators have used these data for dose escalation trials in prostate (RTOG 9406) and lung cancer (RTOG 9311) and obtained two NIH R01 grants focused on the development of normal tissue complication probability (NTCP) models. Also, online access to RTOG 9406 TP data has been used to analyze erectile dysfunction following 3DCRT for prostate cancer. Using the contour editing feature in the RRT, penile bulb structures, not originally contoured for RTOG 9406, were delineated on these datasets. New DVHs were computed from the stored 3D dose distributions and compared with reported clinical outcomes (impotence). Such an analysis would have required an entirely new study if the volumetric TP data had not been archived in the ITC database.

Conclusion: The ITC archive of volumetric images and dosimetry for RTOG Advanced Technology Clinical Trials is a rich resource for developing and testing models of tissue response to ionizing radiation. The value of this archive continues to grow with the incorporation of new data sets from new anatomical sites, and new imaging modalities.

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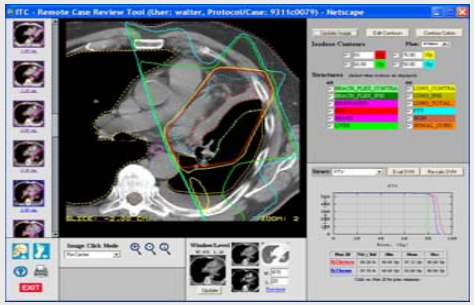
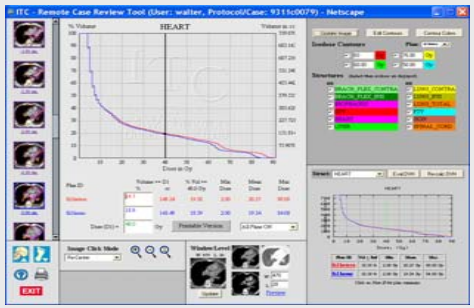
Data Collection and Quality Assurance for RTOG Advanced Technology Clinical Trials

The Image Guided Therapy QA Center (ITC), as part of the Advanced Technology QA Consortium (ATC), collects volumetric treatment planning (TP) data sets linked to outcomes for RTOG Advanced Technology clinical trials.



RRT structure contour, iso-dose display

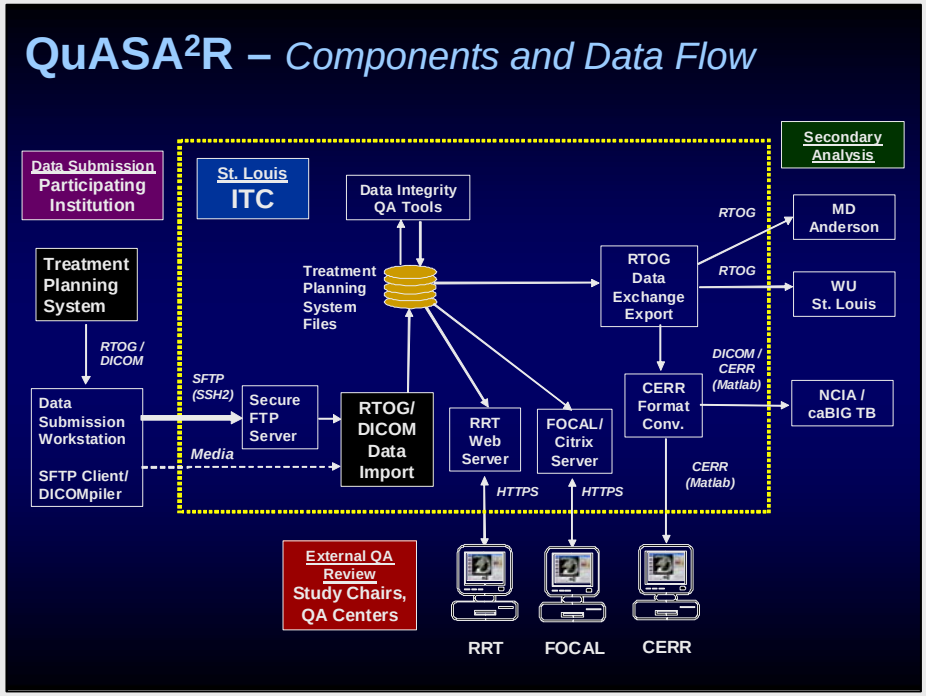


RRT dose-volume analysis display

- CT images, target-volume/organ-at-risk contours, and 3-D dose distributions exported from commercial TP systems are submitted to the ITC using either DICOM or RTOG Data Exchange format.
- ITC staff evaluates **dataset integrity and completeness**, and requests re-submission as needed. Dose-Volume Histograms (DVHs) for required volumes are recalculated from submitted contours and dose distributions.
- RTOG dosimetrists and study chairs review contours and dose distributions for **protocol compliance** using ITC's web-based Remote Review Tool (see screen images below).
- **Clinical outcomes** are reported to RTOG headquarters using protocol-specific forms.
- Dose-volume statistics, computed at ITC from structure contours and 3D Dose distributions, are analyzed with respect to protocol endpoints by RTOG statisticians.
- Volumetric treatment planning data sets are archived for retrospective analysis

QuASA²R: Quality Assurance Submission, Archive, Analysis, and Review System

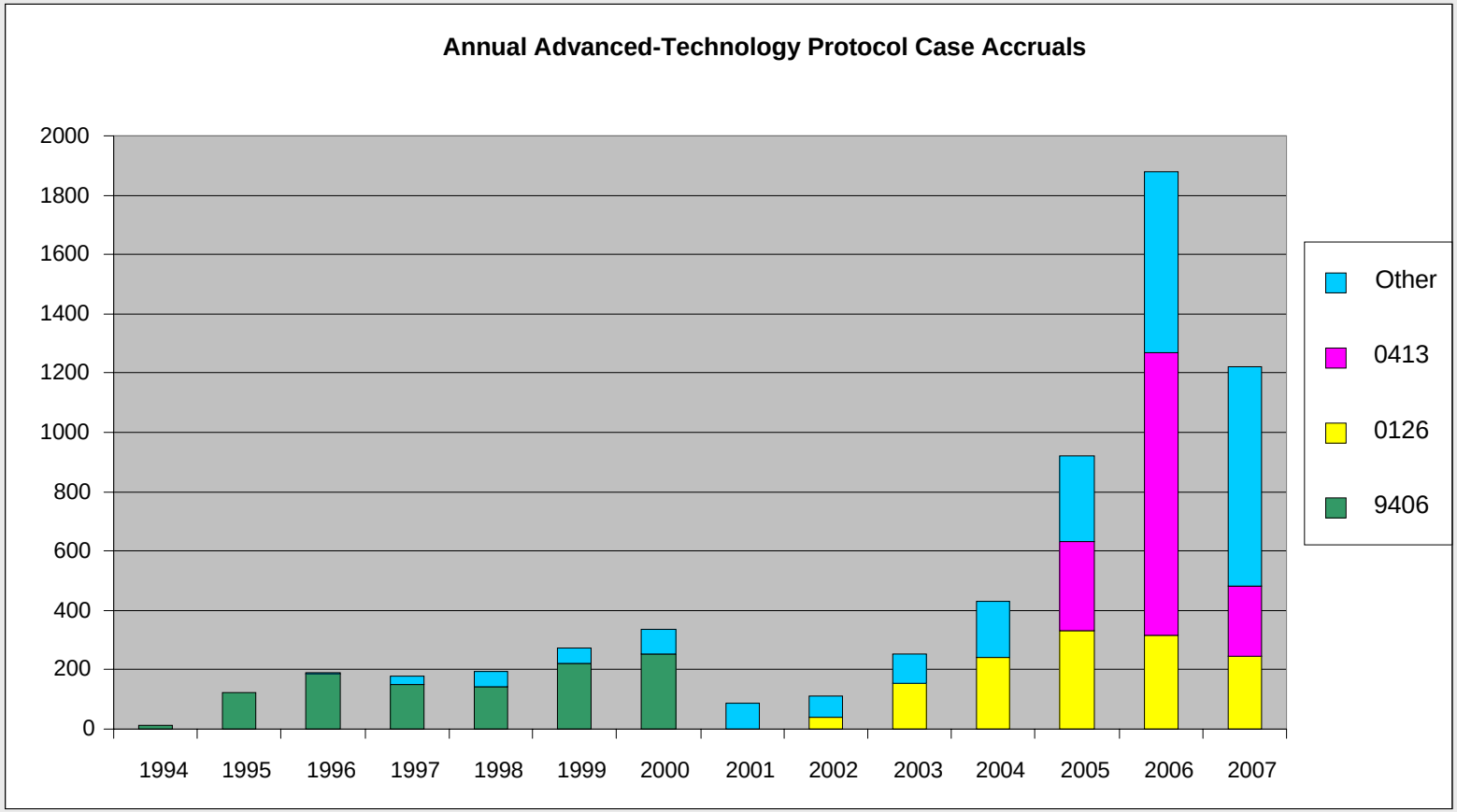
The QuASA²R information infrastructure is used to collect, archive, review and analyze volumetric treatment planning (TP) data sets for RTOG Advanced Technology clinical trials. The components of this system are shown in the diagram below



- Arrows indicate the flow of data from participating institutions, where data are exported from treatment planning systems using the RTOG Data Exchange or DICOM format.
- At the ITC, submitted data are received and imported to prepare them for Quality Assurance Review.
- The data undergo an analysis process referred to as “Data Integrity QA”.
- The protocol case datasets are made available for external protocol compliance review by study chairs and QA center personnel using both thin- and thick-client applications.
- The system also includes several mechanisms for sharing protocol data for secondary analysis, once the QA process is complete.

RESULTS: Digital Data Submitted to ITC

Over the past 14 years, more than 5000 complete treatment planning (TP) data sets have been submitted to the ITC by institutions participating in RTOG Advanced-Technology Trials. The chart below shows the annual accrual of protocols cases for these studies.



RTOG Protocols Contributing to the ITC QuASA²R Archive

Site	Protocol		Open	Data sets*	Rx dose	Organs at Risk
Brain	9803	Brain 3DCRT	N	195		Brain_stem Cerebellum Cerebrum Optic_chiasm Optic_nerve Spinal_cord
Breast	0319	Partial breast 3DCRT	N	53	38.5 Gy	Breast Heart Lung Thyroid
	0413	Partial breast	Y	1315	34 Gy (Brachy) or 38.5 Gy (3DCRT)	Breast Heart Lung Thyroid
GI	0529	Anal canal IMRT	Y	28	54 Gy	Femurs Genitals Iliac_crest Large_bowel Small_bowel
	0438	Liver SBRT	Y	8		Kidney Liver Small_bowel Spinal_cord Stomach
GU	9406	Prostate 3D	N	1062		Bladder Femurs Penile_bulb* Rectum
	0126	Prostate 3D/IMRT	Y	1166	70.2 - 79.2 Gy	Bladder Femurs Penile_bulb Rectum
	0232	Prostate seeds	Y	267	Brachy seeds +/- EBRT (45Gy)	Rectum Urethra
	0415	Prostate hypofractionated	Y	187	73.8 Gy (conv.) or 70 Gy (hypo-frac)	Bladder Femurs Penile_bulb Rectum
	0521	Prostate IMRT	Y	163	72 Gy	Bladder Femurs Penile_bulb Rectum
	0321	Prostate HDR	N	122		Bladder Rectum Urethra
GYN	0418	Cervix IMRT	Y	71	50.4 Gy	Bladder Femurs Rectum Sacrum Small_bowel
H/N	0022	Oropharynx 3DCRT/IMRT	N	68	66 Gy	Brain_stem Larynx Mandible Parotids Spinal_cord Submandib_glands
	0225	Nasopharynx 3DCRT/IMRT	N	65	70 Gy	Brain Brain_stem Larynx Lens Mandible Optic_nerve Optic_chiasm Orbit Parotitds Pituitary Spinal_cord Temporal_lobe TMJ Tongue
	0234	Head/Neck IMRT	Y	79		Spinal_cord
	0435	Head/Neck Palifermin	Y	8	70 Gy	Brachial_plexus Brain_stem Larynx Parotids Spinal_cord
	0522	Head/Neck 3DCRT/IMRT, PET	Y	223	70 Gy	Brachial_plexus Brain_stem Larynx Parotids Spinal_cord
Lung	9311	Lung 3DCRT	N	177		Brachial_plexus Esophagus Heart Liver Lung Spinal_cord
	0117	Lung 3DCRT	Y	57	70 - 75.25 Gy	Esophagus Heart Liver Lung Spinal_cord
	0236	Lung SBRT	N	52		Brachial_plexus Bronchial_tree Esophagus Heart Lung Spinal_cord Trachea
	0515	Lung PET/CT target delineation	Y	9		Carina Heart Liver Lung Spinal_cord

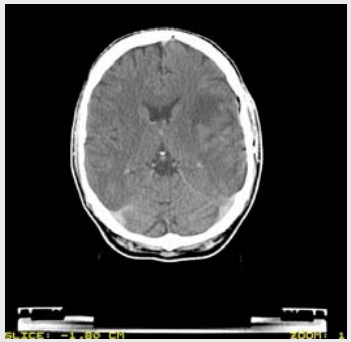
* Data sets include: CT images, Structure Contours, 3D Dose Distributions, and Plans (3DCRT, Brachy seeds)

The ITC QuASA²R Archive includes over 5000 complete TP data sets quantifying the relationship between image-based anatomy and planned doses. Each dataset includes treatment planning CTs, target-volume/organs-at-risk contours, and 3D dose distributions. Treatment plans are available for 3DCRT and brachytherapy seeds.

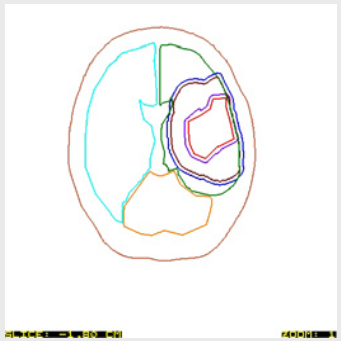
Disease sites treated on 10 closed protocols (1800 cases) include prostate, lung, brain, head/neck, and breast. 13 active protocols (>3500 cases) also include liver, cervix, and anus. The table below outlines the data acquired for each protocol.

ITC QuASA²R Digital Data Archive

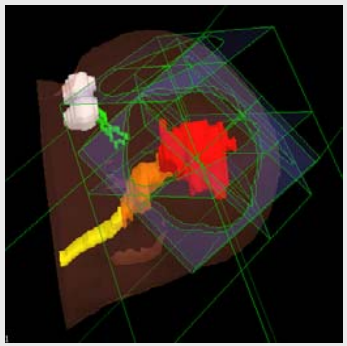
For each protocol case, the following data objects are stored. ITC performs Digital Data Integrity QA to ensure the spatial registration, consistent labeling, and proper scaling of these objects.



- **Volumetric CT images**
- Define patient coordinate system
- Protocol-compliant extent and slice spacing



- **Structure Set**
- Axial slice contours
- Protocol-compliant names for targets, organs-at-risk
- PTVs may include organs-at-risk (i.e., a voxel may belong to both a PTV and an OAR)



- **Treatment Plan (3DCRT and Brachy seeds)**
- Beam geometry and weighting (3DCRT)
- Source locations and strengths (seed brachytherapy)

- **3-D Dose Distribution**
- Absolute dose (Gy)
- Per fraction group
- Fractionation available from treatment record for most protocols.

RESULTS: Sample Dose Volume Statistics

Collection of volumetric dosimetry data has enabled RTOG investigators to perform quality assurance to maintain the consistency of target volumes and organs at risk, allowing meaningful comparison on dose-volume statistics for advanced-technology trials. Having 3-D geometric data for structures has also made it possible to evaluate the size of margins used in treating patients. Sample dose-volume statistics for several data sets are shown at right.

Head & Neck (IMRT, N=64)		Min	Max	Avg	
PTV	D_{98}	58.0	73.4	67.6	Gy
Spinal Cord	D_{mean}	32.8	44.8	39.6	Gy
Parotid	D_{mean}	21.2	50.3	32.4	Gy
Larynx	D_{mean}	3.9	57.7	32.9	Gy
Lung (3DCRT, N=158)		**Min**	**Max**	**Avg**	
PTV	D_{98}	50.3	98.2	77.4	Gy
Spinal Cord	D_2	0.1	60.1	26.0	Gy
Esophagus	D_{mean}	0.0	63.8	15.9	Gy
Heart	D_{mean}	0.0	45.3	10.5	Gy
Liver	D_{mean}	0.0	19.3	1.2	Gy
Brachial Plexus	D_{mean}	0.0	57.7	4.6	Gy
Lung	V_{20}	5.3	46.6	21.2	%
Prostate (3DCRT, N=984)		**Min**	**Max**	**Avg**	
PTV	D_{98}	52.2	81.6	75.0	Gy
Bladder	D_{mean}	4.9	75.9	37.7	Gy
Rectum	D_{mean}	12.9	72.5	42.7	Gy
Femoral Heads	D_{mean}	1.8	49.5	32.4	Gy

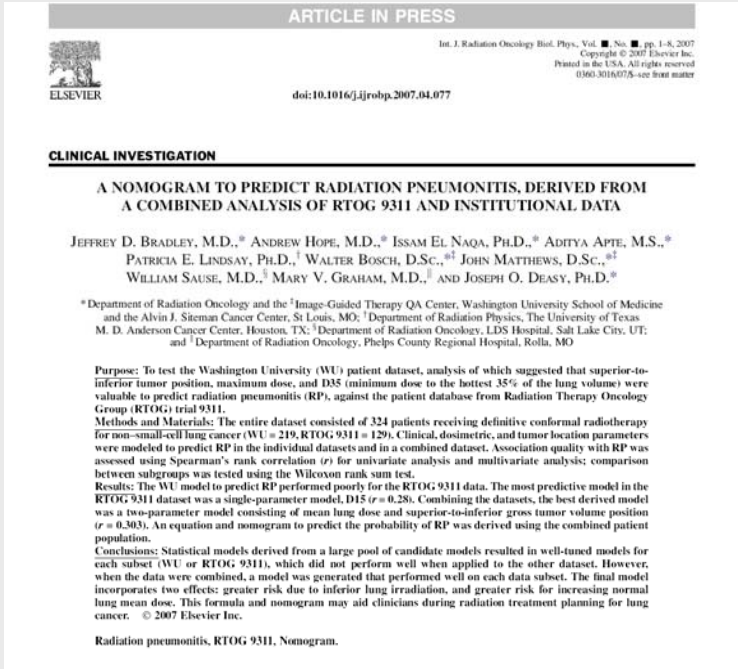
Analysis of Volumetric Dosimetry Data in the ITC Archive

In addition to supporting protocol compliance QA and outcomes analysis for RTOG protocols, the ITC has also provided access to these TP protocol data sets for secondary analysis by: (1) export of entire TP data sets as RTOG data exchange files and (2) online data analysis using the RRT. External investigators have used these data for dose escalation trials in prostate (RTOG 9406) and lung cancer (RTOG 9311) and obtained two NIH R01 grants focused on the development of normal tissue complication probability (NTCP) models. Also, online access to RTOG 9406 TP data has been used to analyze erectile dysfunction following 3DCRT for prostate cancer. Using the contour editing feature in the RRT, penile bulb structures, not originally contoured for RTOG 9406, were delineated on these datasets. New DVHs were computed from the stored 3D dose distributions and compared with reported clinical outcomes (impotence). **Such an analysis would have required an entirely new study if the volumetric TP data had not been archived in the ITC database**.

As a participant in the Cancer Bio-Informatics Grid (caBIG) *In Vivo* Imaging Workspace, the ITC has contributed TP data sets from RTOG Protocol 0522 to the National Cancer Imaging Archive (NCIA). Quantitative pre- and post-treatment PET images acquired for these patients on ACRIN Protocol 4500 are also being submitted to the NCIA repository by ACRIN to enable an evaluation of treatment response.

Secondary Analysis: Lung Toxicity (RTOG 9311)

- RTOG 9311 data were analyzed to investigate lung toxicity (radiation pneumonitis) as a function of dose-volume statistics, as well as the spatial coordinates of the gross tumor volume. Multi-institutional RTOG 9311 data were used to test a statistical model derived from single-institution (Washington University) dataset.
- This study showed that models tuned for each subset (WU or RTOG) did not perform well when applied to the other dataset. However, a model derived from the combined data performed well on each data subset. This exercise indicates the advantage in generating robust models based on multi-institutional datasets. [Bradley et al. 2007].
- Such an analysis would have required an entirely new study if the 3D treatment planning data had not been archived in the ITC QuASA^{2}R database.
- The nomogram shown at right (from Bradley et al., 2007) displays the relationship between pneumonitis risk (requiring steroids or more intensive intervention) and the two most significant variables: Mean normal lung dose and relative position within the lung of the center of the high-dose region (0 = most inferior, 1 = most superior).
- Note that the importance of the position of the high dose region could not have been probed without the complete CT-based dataset.



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CLINICAL INVESTIGATION

A NOMOGRAM TO PREDICT RADIATION PNEUMONITIS, DERIVED FROM A COMBINED ANALYSIS OF RTOG 9311 AND INSTITUTIONAL DATA

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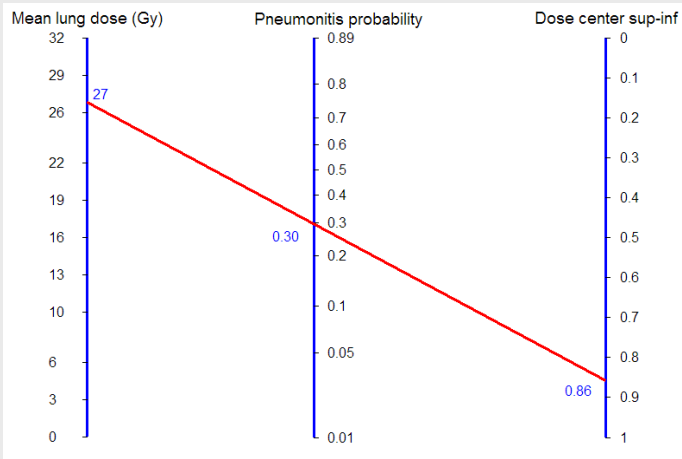
Purpose: To test the Washington University (WU) patient dataset, analysis of which suggested that superior-to-inferior tumor position, maximum dose, and D35 (minimum dose to the hottest 35% of the lung volume) were valuable to predict radiation pneumonitis (RP), against the patient database from Radiation Therapy Oncology Group (RTOG) trial 9311.

Methods and Materials: The entire dataset consisted of 324 patients receiving definitive conformal radiotherapy for non–small-cell lung cancer (WU = 219, RTOG 9311 = 129). Clinical, dosimetric, and tumor location parameters were modeled to predict RP in the individual datasets and in a combined dataset. Association quality with RP was assessed using Spearman's rank correlation (r) for univariate analysis and multivariate analysis; comparison between subgroups was tested using the Wilcoxon rank sum test.

Results: The WU model to predict RP performed poorly for the RTOG 9311 data. The most predictive model in the RTOG 9311 dataset was a single-parameter model, D15 ($r = 0.28$). Combining the datasets, the best derived model was a two-parameter model consisting of mean lung dose and superior-to-inferior gross tumor volume position ($r = 0.303$). An equation and nomogram to predict the probability of RP was derived using the combined patient population.

Conclusions: Statistical models derived from a large pool of candidate models resulted in well-tuned models for each subset (WU or RTOG 9311), which did not perform well when applied to the other dataset. However, when the data were combined, a model was generated that performed well on each data subset. The final model incorporates two effects: greater risk due to inferior lung irradiation, and greater risk for increasing normal lung mean dose. This formula and nomogram may aid clinicians during radiation treatment planning for lung cancer.

Radiation pneumonitis, RTOG 9311, Nomogram.



Secondary Analysis: GI Toxicity (RTOG 9406)

RTOG 9406 data have been analyzed by Dr. Sue Tucker and colleagues to investigate rectal toxicity. The ITC has provided access to TP data for this protocol, and RTOG has provided clinical staging and outcome data for secondary analysis. Dr. Tucker was successful in obtaining an NIH R01 grant investigating the use of these data sets for developing normal tissue complication probability (NTCP) models [See CRISP abstract at right].

Results of this analysis are being presented at this meeting. [See abstracts #15 and #16.]

Version 2.5.2.0

CRISP

Abstract

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Grant Number: 5R01CA104342-03
Project Title: Dose-Volume Modeling of Late Rectal and Bladder Toxicity

PI Information: Name	Email	Title
TUCKER, SUSAN L.	sltucker@mdanderson.org	PROFESSOR

Abstract: *DESCRIPTION (provided by applicant): Carcinoma of the prostate is the most commonly occurring cancer among men in the United States, and is second only to lung cancer in terms of the number of cancer-related deaths in this group. The American Cancer Society estimated an age-adjusted incidence of more than 190,000 newly diagnosed cases of prostate cancer in the U.S. during the year 2000, with more than 35,000 deaths. Radiotherapy (RT) is one of the primary treatment modalities for prostate cancer, but the radiation doses used for: conventional RT are limited by the need to avoid severe complications to adjacent normal tissues, notably the rectum and bladder. Technological advances such as 3- dimensional conformal RT (3D-CRT) and intensity-modulated RT (IMRT) allow radiation dose distributions that conform much more tightly to the prostate gland than with conventional RT, allowing safe dose escalation and improved tumor control, but the need for further improvement remains. Moreover, with increasing numbers of patients experiencing tumor control after RT, there is an increasing need to improve the quality of life among prostate cancer survivors by reducing the risk of normal-tissue toxicity. Since the range of possible conformal RT plans is enormous, quantitative methods are vitally needed to assess and compare large numbers of possible plans, in order to select the safest and most effective plan for each patient. We propose to develop quantitative models for the risk of late rectal and bladder toxicity as a function of the dose distribution received by those organs during treatment. The models will be derived by analyzing the data from protocol 94-06 of the Radiation Therapy Oncology Group of the American College of Radiology. Protocol RTOG 94-06, entitled "A Phase I/II Dose Escalation Study Using Three Dimensional Conformal Radiation Therapy for Adenocarcinoma of the Prostate" (Principal Investigator James D. Cox, M.D.), was a multi-institutional trial designed to establish the maximum radiation dose that can be tolerated by surrounding tissues during 3D-CRT of the prostate. The trial enrolled 1084 patients from 35 different institutions from May 1994 to October 2000. The dose distributions to rectum and bladder were accurately recorded, and normal-tissue toxicity has been carefully and consistently measured. Further, the data have mature patient follow-up and come from a large and representative sample of patients treated nationwide using high-quality 3D-CRT, with a sufficient variation in treatment designs to allow us to separate the effects of dose and volume of organ irradiated on the risk of normal-tissue injury. The quantitative dose-volume models developed in this study will be validated by testing their ability to predict complications in two different clinical data sets collected independently. We expect the results of our analyses to play an important role in furthering the development of conformal techniques in RT of the prostate and other pelvic sites.*

Secondary Analysis: GU Toxicity (RTOG 9406)

- RTOG 9406 data were analyzed to investigate GU toxicity (impotence) as a function of dose to Penile Bulb, a structure not originally delineated in the RTOG 9406 data. Online access to the RTOG 9406 TP data sets was provided to Dr. Mack Roach for an investigation of erectile dysfunction following 3D conformal RT for prostate cancer. Using the contour editing feature in the ITC Remote Review Tool, Dr. Roach retrospectively delineated penile bulb structures in RTOG 9406 datasets and new DVHs were computed from the 3D dose distributions archived for these patients and compared with reported clinical outcomes (impotence) [Roach 2004].
- This study showed that patients whose median penile dose was >52.5 Gy had a greater risk of impotence compared with those receiving <52.5 Gy ($p \leq 0.039$) and concluded that dose to the bulb of the penis seems to be associated with the risk of radiation-induced impotence. Such an analysis would have required an entirely new study if the volumetric TP data had not been archived in the ITC QuASA^{2}R database.
- Figure at right shows an example of one case included in this study. Isodose lines for 6000, 5250, 4500, and 3500 cGy moving outward are shown . Penile bulb is also shown with a dotted line in the lower three panels.

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CLINICAL INVESTIGATION — Prostate

PENILE BULB DOSE AND IMPOTENCE AFTER THREE-DIMENSIONAL CONFORMAL RADIOTHERAPY FOR PROSTATE CANCER ON RTOG 9406: FINDINGS FROM A PROSPECTIVE, MULTI-INSTITUTIONAL, PHASE I/II DOSE-ESCALATION STUDY

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Purpose: To assess the relationship between the dose to the bulb of the penis and the risk of impotence in men treated on Radiation Therapy Oncology Group (RTOG) 9406.

Methods and Materials: Men enrolled on a Phase I/II dose-escalation study, RTOG 9406, who were reported to be potent at entry and evaluable ($n = 158$) were selected for inclusion. Follow-up evaluations were scheduled every 3, 4, and 6 months for the first, second, and the third through fifth years, then annually. At each follow-up visit an assessment of potency status was made. Penile structures were defined by a single observer blinded to the potency status, using Web-based, on-line software. The dosimetry for penile structures was calculated at the Quality Assurance Center at Washington University and provided to RTOG Statistical Headquarters to determine whether there was a relationship between dose and impotence.

Results: Patients whose median penile dose was ≥52.5 Gy had a greater risk of impotence compared with those receiving <52.5 Gy ($p = 0.039$). In a multivariate analysis neither age, the dose to the prostate, nor the use of hormonal therapy correlated with the risk of impotence.

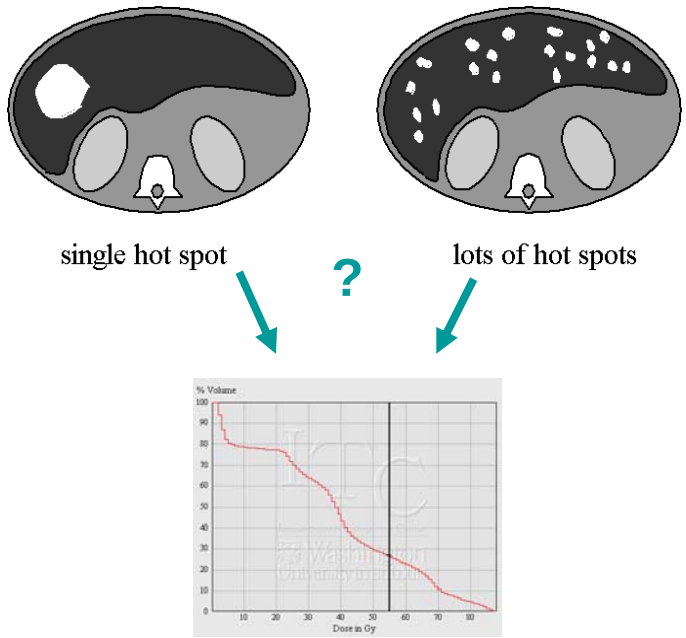
Conclusions: Dose to the bulb of the penis seems to be associated with the risk of radiation-induced impotence.

Prostate cancer, Three-dimensional conformal radiotherapy, Impotence.

Discussion: Why Collect Volumetric Data?

The substantial effort required to acquire volumetric images and dosimetry data invites the question, “Why not just collect DVHs?”

1. The effect of radiation may vary depending on location within an organ (cf. panel 9). However, DVHs do not retain spatial information; only the aggregate volume of a structure at a given dose is counted.
2. Without volumetric data, it is not possible to detect and correct contouring inconsistencies.
3. Without volumetric data, it is not possible to compute dose statistics for volumes other than those in submitted DVHs.
4. Without volumetric data, it is difficult or impossible to determine which structures are included or excluded in a DVH (e.g., “LUNG – PTV” *versus* “LUNG – GTV”).
5. DVHs calculated using different commercial treatment planning systems have been shown to be inconsistent (Straube, et. al., Med Phys, 2005),



Different dose distributions throughout an organ may lead to different expectations of toxicity for some organs. However, DVH statistics do not distinguish between a single, large hot spot and multiple, smaller hot spots.

Summary and Conclusions

- The ITC QuASA^{2}R archive has supported data integrity QA and protocol compliance QA for RTOG Advanced Technology Clinical Trials, enabling the acquisition of more than 5000 complete treatment planning datasets, evaluated for data integrity and protocol compliance, for outcomes analysis in these studies.
- The ITC archive has enabled secondary analysis of RTOG data sets by several investigators. Such investigations would have required new studies if the volumetric TP data had not been archived in the ITC database.
- Anonymized RTOG 0522 data are being made available to the National Cancer Imaging Archive with quantitative pre- and post-treatment PET images (from ACRIN) to enable a functional-imaging-based evaluation of treatment response.
- It is our intent to make anonymized data from other protocols available for secondary analysis via the NCI Cancer Bio-Informatics Grid (caBIG).
- The ITC QuASA^{2}R archive of volumetric images and dosimetry for RTOG Advanced Technology Clinical Trials is a rich resource for developing and testing models of tissue response to ionizing radiation. The value of this archive continues to grow with the incorporation of new data sets from new anatomical sites and new imaging modalities.
- Investigators wishing to request access to ATC data sets should download ***Guidelines for Requests for ATC Data by Investigators*** on the ATC website Resources page (http://atc.wustl.edu/resources).

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