

PILOT STUDY: INTEROBSERVER RELIABILITY OF CT-DERIVED PRIMARY TUMOR VOLUME MEASUREMENT IN PATIENTS WITH SUPRAGLOTTIC CARCINOMA ENROLLED INTO THE RANDOMIZED TRIAL RTOG 91-11

(Data on participant eligibility, demographic characteristics, and follow-up will be provided by RTOG)

Study Investigators:

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Status:

Open

Statistician:

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Activation Date:

June 1, 2001

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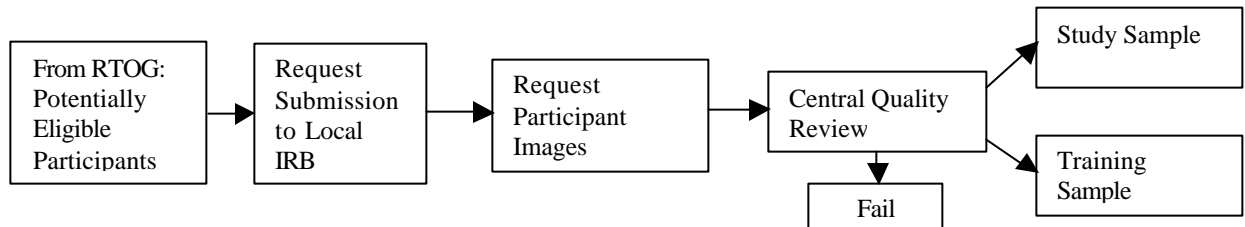
Regulatory Managers:

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Research Trainer for Diagnostic Imaging:

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Schema



Objectives

1. Primary Aim: To determine whether PTV derived from CT is measured reliably across readers.
2. Secondary Aims:
 1. To determine whether volumes of abnormal lymph nodes in the neck are measured reliably across readers.
 2. To train additional readers in the technique of measuring tumor and lymph node volumes.
 3. To assess availability of CT scans from those requested, and quality of CT scans received.
 4. To explore relationships among PTV, volume of abnormal lymph nodes, laryngeal cartilage invasion, T- and N-stage (see Appendix I), local control, and survival.

Participant Population

This retrospective study will use CT exams collected from participants with squamous cell carcinoma of the supraglottic larynx (SGSCCA) enrolled into the radiation therapy only arm of RTOG 91-11. Every effort will be made to include participants of all ethnicities and genders. Criteria for inclusion/exclusion are:

Inclusion criteria:

1. Participants enrolled into RTOG 91-11, with SGSCCA, from an RTOG institution (*including affiliate institutions*), randomized into the “definitive RT only” arm of RTOG 91-11.
2. Informed consent for RTOG 91-11 includes consent to have data obtained in that trial used in further research as long as participant confidentiality is maintained.

Exclusion criteria:

1. CT exam not obtained upon entering RTOG 91-11.
2. CT exam that does not meet minimum specifications outlined in RTOG 91-11.
3. Participants shown upon retrospective review to be ineligible for RTOG 91-11, or who did not start the randomly assigned treatment on RTOG 91-11.

Summary of Study Design

RTOG provided a list of institutions and potentially eligible participants to the ACRIN Regulatory Manager. The Regulatory Manager contacted institutions to track progress through their local IRBs. Once an institution notified ACRIN of IRB approval, the Regulatory Manager sent a request for participant CT exams to the institution. The institution then returned hard-copy CT exams to the American College of Radiology’s (ACR’s) Philadelphia office, or provided reasons why these were not submitted. After logging receipt of CT exams, the Regulatory Manager forwarded the films to the PI for quality review. Following quality review, the PI returned the films to the ACR.

Eight radiologists will interpret the CT exams for each of 20 participants with SGSSCA. Readers will first provide a rating of the quality of each CT exam. They will then measure primary tumor volumes and volumes of abnormal lymph nodes in the neck, and evaluate each CT exam for the presence of laryngeal cartilage invasion. Information regarding participant demographics, characteristics of disease, and participant outcomes will be provided by RTOG.

Per Case Reimbursement: \$500.00

Accrual Goals

Images of sufficient quality from 20 participants were to be accrued. Additional images of sufficient quality will be used for reader training.

Progress to Date

The information in this Progress Report is based on data as of January 31, 2002. 41 institutions with potentially eligible participants were invited to participate in this study; 8 received local IRB approval between June 30, 2001 and November 17, 2001, and 3 declined. CT exams for 36 participants at the 8 institutions with local IRB approval were requested for this study, of which 28 were submitted to the ACR between September 19, 2001 and December 20, 2001, and 24 passed quality review. Image interpretations will occur after software has been validated at the ACR.

Registration by Institution

Data as of January 31, 2002

<u>Institution</u>	<u>Total Reg.</u>
Elliot Hospital	2
H. Lee Moffitt Cancer Center	6
Maine Medical Center	2
Medical College of Wisconsin	1
University of Texas – MD Anderson	9
Washington University	2
Wayne State University	2
Total (7 Institutions)	24

Registration and Quality Review

Data as of January 31, 2002

	<u>Number</u>
NUMBER POTENTIALLY ELIGIBLE	93
NUMBER AT SITES THAT DECLINED	5
NUMBER AT SITES WITHOUT IRB APPROVAL	52
NUMBER AT SITES WITH IRB APPROVAL	36
NUMBER SUBMITTED	28
INSUFFICIENT QUALITY	4
Disease in tongue base, not larynx	1
Disease in true vocal cord, not supraglottic	1
Site submitted chest CT, not neck CT	1
Poor copy quality, irremediable	1
SUFFICIENT QUALITY	24