



SBRT LUNG CANCER CLINICAL PATHWAY

Final Draft – March 2015

Cancer Clinical Performance Group –Radiation Oncology SBRT Workgroup

Membership:

Rex Hoffman, MD, Clinical Lead, Disney Family Cancer Center (Burbank, CA)

Vivek Mehta, MD, Swedish (Seattle, WA)

Bill Barnes, Providence Alaska (Anchorage, AK)

Jamie Blom, MD, Providence Alaska (Anchorage, AK)

John Halligan, MD, Providence Alaska (Anchorage, AK)

Steven Seung, MD, PhD, Providence Portland (Portland, OR)

Marka Crittenden, MD, PhD, Providence Portland (Portland, OR)

Jeffrey Stephenson, MD, Providence St. Patrick (Missoula, MT)

Jin-Song Ye, Swedish (Seattle, WA)

Jianzhou Wu, Swedish (Seattle, WA)

Ron Houston, Providence Alaska (Anchorage, AK)

Nancy Wingate, Providence Alaska (Anchorage, AK)

Christopher Loiselle, MD, Swedish (Seattle, WA)

James Raymond, MD, RadiantCare (Olympia, WA)

Darren Little, MD, Providence Regional (Everett, WA)

Lung SBRT Clinical Guidelines

1. Clinical indications

- Patient Inclusion criteria
- Patient Exclusion criteria

2. Equipment Requirements

- CT scanner for simulation
- Immobilization devices
- Tumor Tracking/Limitation of Movement
- Treatment Planning System components
- Treatment Machine

3. Treatment Planning

Quality Control

Simulation and Treatment

Positioning and Immobilization

Respiratory Tracking Control Techniques and Simulation

Treatment Planning

Target Delineation

Planning Instructions and Evaluation

Dose prescription

Plan evaluation

4. Treatment Delivery and Verification

5. Quality Assurance

Quality assurance of input/output devices

Quality assurance of treatment machines

Quality assurance of treatment planning systems

“End-to-end” test

Patient specific quality assurance

6. Post Treatment Supportive Care

Clinical Indications

Patient Inclusion Criteria

1. Prior to lung SBRT, patients are highly recommended to be evaluated by an experienced thoracic surgeon and/or presented at MDTC to determine resectability.
2. Patient is deemed medically inoperable or prefers SBRT over surgery.
3. Clinical stage T1-T2, N0,M0 (AJCC 7th edition)
4. KPS > 60 or ECOG <3.
5. Size < 5 cm. (Tumor > 5 cm may be considered in select cases if dose conformity and normal tissue constraints are met.)
6. Central lesions (within 2 cm from main airways and proximal bronchial tree) or lesions adjacent to the chest wall should be treated at the discretion of the treating physician after a thorough discussion with the patient.
7. Tissue confirmation of non small cell lung cancer is preferred. It is acceptable to treat patients without pathological confirmation if there is clinical evidence (growth on CT scans or positive PET scan.)
8. Recurrent lung cancer after previous surgery or radiation therapy may be treated at the discretion of the treating physician.

Patient Exclusion Criteria

1. Life Expectancy less than 6 months.
2. Inability to tolerate treatment position.
3. Being treated for a significant active infection.
4. Pulmonary function tests are not used to exclude patients from SBRT as long as they can lie down during treatment.

Equipment Requirements

1. CT scanner for Simulation - evaluate breathing mobility

Examples:

- 4D CT
- Multi-slice CT
- Dynamic scans (repeated scans at the same couch position)
- Evaluation of tumor at max inspiration and max expiration
- Slow CT (eg. Scan time/slice of 3 seconds)

2. Immobilization Devices

Examples:

- Body Fix
- Body Pro Lock
- Alpha Cradle

3. Tumor Tracking/Limitation of Movement:

Examples:

- Abdominal compression
- Gating
- Real-time tracking

4. Treatment Planning System components:

- Heterogeneity correction capability
- Algorithm (pencil beam, Monte Carlo or superposition/convolution)
- Image registration tools for geometric verification
- DVH tools

5. Treatment Machine

Linear Accelerator or Cyberknife that has the following components:

- Image Guided Radiation Therapy
- Max MLC leaf width 1 cm

- 6 MV photons
- Preferred dose rate: at least 400 MU/min (using the highest dose rate available)

Treatment Planning

QUALITY CONTROL

The accuracy and precision of SBRT treatment planning and delivery are paramount and requires reproducible immobilization or positioning maneuvers.

Efforts need to be made to account for inherent organ motion that might influence target precision.

Dose distributions surrounding the target with rapid falloff to normal tissue are achieved by using numerous beams or large arcs of radiation with carefully controlled aperture shapes, as well as with intensity-modulated radiation delivery.

Stereotactic targeting and treatment delivery ensure that these beams will travel with the highest precision to their intended destination.

The images used in SBRT are critical to the entire process. The quality of patient care and treatment delivery is predicated on the ability to define the target and normal tissue boundaries as well as to generate target coordinates at which the treatment beams are to be aimed. They are used for creating an anatomical patient model (virtual patient) for treatment planning, and they contain the morphology required for the treatment plan evaluation and dose calculation.

General consideration should be given to the following issues. The targeting of lesions for SBRT planning may include general radiography images, CT, MRI, PET (with or without image fusion), or any other imaging studies useful in localizing the target volumes. Digital images used for SBRT must be thoroughly investigated and then corrected for any significant spatial distortions that may arise from the imaging chain. CT is the most useful, spatially undistorted, and practical imaging modality for SBRT. It permits the creation of the 3D anatomical patient model that is used in the treatment planning process. Some CT considerations are the following: partial volume averaging, pixel size, slice thickness, distance between slices, and timing of CT with respect to contrast injection, contrast washout, and image reformatting for the treatment planning system, as well as potential intra-scan organ movement.

Documentation must exist indicating that the medical physicist has authorized the system for clinical use and has established a quality assurance(QA) program to monitor the 3D system's performance as it relates to the 3D planning process. Data input from medical imaging devices is used in conjunction with a mathematical description of the external radiation beams to produce an anatomically detailed patient model illustrating the dose distribution with a high degree of precision. Furthermore, it is recognized that various testing methods may be used, with equal validity, to assure that a system feature or component is performing correctly. It is also noted that the commercial manufacturer may recommend specific QA tests to be performed on its planning systems. For these reasons, the method and testing frequency are not specified.

Maintain an ongoing system log indicating system component failures, error messages, corrective actions, and system hardware/software changes.

SIMULATION AND TREATMENT

The tolerance for radiation targeting accuracy, which includes accounting for systematic and random errors associated with setup and target motion, needs to be determined for each different organ system in each department performing the SBRT by actual measurement of organ motion and setup uncertainty.

Positioning and Immobilization

The frame-based stereotaxy fiducials are rigidly attached to non-deformable objects reliably registered to the target. Given potential changes in the internal location of mobile tumors relative to external frames, frame-based methods are generally supplemented with some form of pretreatment image guidance to confirm proper tumor relocalization.

Frameless stereotaxy uses the fiducials that are registered immediately before or during the targeting procedure. Examples of frameless stereotaxy include image capture of 1 or more metallic seeds (each constituting a single “point” fiducial) placed within a tumor, using surrogate anatomy such as bone (constituting a volumetric fiducial) whose position is well established in relation to the target, or using the target itself (e.g., identified on the image guidance system) as a fiducial.

The patient is positioned appropriately with respect to the stereotactic coordinate system used, ensuring that the target is within physically attainable fiducial space. The treatment position should be comfortable enough for the patient to hold still for the entire duration of the SBRT procedure. Immobilization may involve use of a body aquaplast mold, a thermoplastic mask, a vacuum mold, a vacuum pillow, immobilization cushions, etc.

Respiratory Tracking Control Techniques and Simulation

This activity may use a variety of methods, including 4D CT, respiratory gating, tumor tracking, organ motion dampening, or patient-directed methods. Once the patient is properly positioned, bony landmarks registering the patient within the stereotactic coordinate system being used are identified and marked by the radiation oncologist. Abdominal compression, if used, is applied to a degree that is tolerable and limits tumor or diaphragm movement. The limitation of tumor and diaphragm movement may be verified by fluoroscopic examination. The CT simulation is performed with the patient in the treatment position, and the errors added by the fusion algorithm are quantified and included in the uncertainty shell produced by the clinical target volume (CTV) to planning target volume (PTV) expansion.

Treatment Planning

Treatment planning involves contouring of gross tumor volume (GTV) and the normal structures, review of iterations of treatment plans for PTV adequate dose coverage, review of proper fall off gradients, and review of dose/volume statistics by the radiation oncologist. Every effort should be made to minimize the volume of surrounding normal tissues exposed to high dose levels. This requires minimizing the consequential high dose (i.e., dose levels on the order of the prescription dose) resulting from entrance of beams, exit of beams, scatter radiation, and enlargement of beam apertures required to allow for target position uncertainties. The target dose distribution conforms to the shape of the target, thereby

avoiding unnecessary prescription dose levels occurring within surrounding normal tissues. Quantification of the dose/volume statistics for the surrounding tissues and organs is needed so that volume- based tolerances are not exceeded. It should be understood that reduction of high dose levels within normal tissue volume may require additional exposure of normal tissues to low dose levels (i.e., increased integral dose).

Target Delineation:

Gated scan/treatment (4D) with or without CT with compression:

- 4D CT
- Contour an internal target volume (ITV) (on all phases of 4D scan and/or MIP)
- Recommend 3-5mm margin on ITV

Non-Gated scan/treatment (4D)

On the scan, contour the visible target GTV utilizing lung windows (use PET scan for visual guidance)

- Fuse the PET and planning scans and consider using Boolean operators to create an “ITV”

Planning Instructions and Evaluation:

Dose prescription

The prescription should include the number of treatment fractions and total treatment delivery period. For example: 18Gy per fraction for a total of 3 fractions (Total dose 54Gy) for peripheral lesions. 10 Gy per fraction for a total of 5 fractions (Total dose 50 Gy) for centrally located lesions. Dose constraints accepted by nationally recognized bodies such as RTOG are recommended.

Plan evaluation

Treatment plan should be evaluated and approved by the radiation oncologist and physicist. The following dosimetric parameters used for plan evaluation are based on RTOG 0618, and 0813.

- View isodose on every slice: look for notable areas of high or low dose outside of the PTV

Dosimetry Objectives and Constraints *(based on typical 3 fraction SBRT adapted from RTOG 0618))*

Organ	Volume	Dose (cGy)
Spinal Cord	Any point	18 Gy (6 Gy per fraction)
Esophagus	Any point	27 Gy (9 Gy per fraction)
Ipsilateral Brachial Plexus	Any point	24 Gy (8 Gy per fraction)
Heart/Pericardium	Any point	30 Gy (10 Gy per fraction)
Trachea and Ipsilateral Bronchus	Any point	30 Gy (10 Gy per fraction)
Whole Lung (Right & Left)	(See table in Section 6.4.2)	(See table in Section 6.4.2)
Skin	Any point	24 Gy (8 Gy per fraction)

Dosimetry Objectives and Constraints (based on typical 5 fraction SBRT adapted from RTOG 0813))

Serial Tissue	Volume	Volume Max (Gy)	Max Point Dose (Gy)	Avoidance Endpoint
Spinal Cord	<0.25 cc <0.5 cc	22.5 Gy (4.5 Gy/tx) 13.5 Gy (2.7 Gy/tx)	30 Gy (6 Gy/tx)	myelitis
Ipsilateral Brachial Plexus	<3 cc	30 Gy (6 Gy/tx)	32 Gy (6.4 Gy/tx)	neuropathy
Skin	<10 cc	30 Gy (6 Gy/tx)	32 Gy (6.4 Gy/tx)	ulceration
Parallel Tissue	Critical Volume	Critical Volume Dose Max (Gy)		Avoidance Endpoint
Lung (Right & Left)	1500 cc	12.5 Gy (2.5 Gy/tx)		Basic Lung Function
Lung (Right & Left)	1000 cc	13.5 Gy (2.7 Gy/tx)		Pneumonitis
Serial Tissue*	Volume	Volume Max (Gy)	Max Point Dose (Gy)	Avoidance Endpoint
Esophagus, non-adjacent wall	<5 cc	27.5 Gy (5.5 Gy/tx)	105% of PTV prescription	stenosis/fistula
Heart/Pericardium	<15 cc	32 Gy (6.4 Gy/tx)	105% of PTV prescription	pericarditis
Great vessels, non-adjacent wall	<10 cc	47 Gy (9.4 Gy/tx)	105% of PTV prescription	aneurysm
Trachea and ipsilateral bronchus, non-adjacent wall	<4 cc	18 Gy (3.6 Gy/tx)	105% of PTV prescription	stenosis/fistula

Conformality guidelines based on RTOG 0618, and 0813

Maximum PTV Dimension (cm)	Ratio of Prescription Isodose Volume to the PTV		Ratio of 30 Gy Isodose Volume to the PTV, $R_{30\text{ Gy}}$		Maximum Dose 2 cm from PTV in any Direction, $D_{2\text{cm}}$ (Gy)		Percent of Lung receiving 20 Gy total or more, V_{20} (%)		PTV Volume (cc)
	Deviation		Deviation		Deviation		Deviation		
	none	minor	none	minor	none	minor	none	minor	
2.0	<1.2	1.2-1.4	<3.9	3.9-4.1	<28.1	28.1-30.1	<10	10-15	1.8
2.5	<1.2	1.2-1.4	<3.9	3.9-4.1	<28.1	28.1-30.1	<10	10-15	3.8
3.0	<1.2	1.2-1.4	<3.9	3.9-4.1	<28.1	28.1-30.1	<10	10-15	7.4
3.5	<1.2	1.2-1.4	<3.9	3.9-4.1	<28.1	28.1-30.1	<10	10-15	13.2
4.0	<1.2	1.2-1.4	<3.8	3.8-4.0	<30.4	30.4-32.4	<10	10-15	21.9
4.5	<1.2	1.2-1.4	<3.7	3.7-3.9	<32.7	32.7-34.7	<10	10-15	33.8
5.0	<1.2	1.2-1.4	<3.6	3.6-3.8	<35.1	35.1-37.1	<10	10-15	49.6
5.5	<1.2	1.2-1.4	<3.5	3.5-3.7	<37.4	37.4-41.7	<10	10-15	69.9
6.0	<1.2	1.2-1.4	<3.3	3.3-3.5	<39.7	39.7-41.7	<10	10-15	95.1
6.5	<1.2	1.2-1.4	<3.1	3.1-3.3	<42.0	42.0-44.0	<10	10-15	125.8
7.0	<1.2	1.2-1.4	<2.9	2.9-3.1	<44.3	44.3-46.3	<10	10-15	162.6

Treatment Delivery and Verification

Physics presence required at delivery of first dose and recommended for subsequent doses based on AAPM TG-101. Physician presence required at each fraction. Precision should be validated by the QA process and maintained throughout the entire treatment process. The radiation oncologist is responsible for assuring that patient positioning and field placement are accurate for each fraction. The image-guided stereotactic procedure is used to verify or correct the patient's position relative to the planning image data set. However, it is important to point out that any electrical, software, or mechanical malfunctions that disturb the connection between the image guidance system and the treatment delivery system can produce erroneous results that are not easily detected through visual examination of the patient's position in the treatment room. In those situations where the target or an acceptable surrogate can be seen with the aid of an imaging procedure that uses the treatment beam, verification of the target position is possible. When the image guidance system does not use the treatment beam and no secondary system is available, the QA test described above is the only reasonable way of determining that the overall imaging plus treatment delivery system is communicating properly.

Quality Assurance:

The treatment-delivery unit requires the implementation of, and adherence to, an ongoing QA program. Precision should be validated by a reliable QA process.

Quality assurance of input/output devices:

Check the input devices for functionality and accuracy of the image-based planning systems for medical imaging data (CT, MRI, PET, etc.), input interfaces, or digitizers. Assure correct anatomical registration: left, right, anterior, posterior, cephalad, and caudad from all the appropriate input devices.

Assure functionality and accuracy of all printers, plotters, and graphical display units that use digitally reconstructed radiographs (DRRs) or the like to produce a beam's-eye-view rendering of anatomical structures near the treatment beams isocenter. Assure correct information transfer and appropriate dimensional scaling.

Quality assurance of treatment machines:

SBRT QA must guarantee that both the image-guided system and the treatment delivery system are functioning within acceptable tolerances. In addition, it is essential that the QA process also guarantees that these 2 systems communicate such that the information gathered by the imaging system properly directs the selected beams to the position within the patient determined by the treatment planning process. It is not acceptable to test the 2 systems separately. Instead, tests must be devised that tie them together. This procedure must be a two-step process: the first step must be designed to use the image-guided system to position 1 or more test points, e.g., fiducials, in space at known coordinates. The second step must work through the treatment planning system to irradiation of these test points with the actual treatment beam, using an appropriate imaging technique that verifies acceptable target localization. In addition, it is essential to perform machine routine quality assurance tests following TG 142 protocol.

Quality assurance of treatment planning systems:

Assure the continued integrity of the planning system information files used for modeling the external radiation beams. Verify transfer of multileaf collimator data and other treatment-related parameters. Confirm agreement of the beam modeling with currently accepted clinical data derived from physical measurements. Small field beam data should be measured with proper dosimeters by qualified physicists. Similarly, assure the integrity of the system to render the anatomical modeling correctly.

Once the individual components of the SBRT planning and treatment technique are commissioned, it is recommended that the QA program include an operational test of the SBRT system. This test should be performed before proceeding to treat patients. The operational test should mimic the patient

treatment and should use all of the same equipment used for treating the patient. An added benefit to the above approach is the training of each team member for his/her participation in the procedure.

“End-to-end” test:

Prior to the commencement of lung SBRT, it is highly recommended to perform an “end-to-end” test to ensure the accuracy and integrity of the overall system and process.

Patient specific quality assurance:

Patient specific QA should be performed prior to the first treatment.

1. Treatment plan transfer to V&R system

Reference CT and treatment plan parameters such as beam energy, MU, field size, gantry/collimator/couch angles, MLC leaf positions, beam modifier, etc. are transferred to V&R system from the treatment planning system. Treatment isocenter on the reference CT and these treatment parameters should be verified by a physicist to ensure that there is no error in data transfer.

2. Independent beam MU verification for 3D CRT plans

MUs of the plan should be verified with an independent calculation for 3D CRT plan either by hand-calculation or by a secondary computer MU calculation program, and IVD measurements are to be performed in the first treatment fraction. The differences between the IVD measurement and the expected value should be within 5%.

3. Quality assurance for VMAT and IMRT plans

For IMRT/VMAT treatment, QA measurement with a phantom, including absolute point doses and 2D dose distributions, should be performed, analyzed and approved by the physicist prior to the first treatment delivery. For 3mm and 3% criteria, the pass rate is recommended to be at least 90%.

4. Dry run prior to treatment delivery

Dry run session should be performed prior to the first treatment, make sure no collision between the gantry/linac head and the patient.

5. Image registration for image guided radiation therapy

CBCT or 4D-CBCT is acquired prior to the delivery of the treatment. Daily Cone Beam CT images are registered to the reference CT images for localization. A physicist and a radiation oncologist should work together to approve the registration result for CBCT guided treatment. A physician should verify the port films before every fraction of the SBRT treatment. Physicist should be present during the treatment.

Post-Treatment Supportive Care

1. Generate Cancer Treatment Summary – See Appendix 1 for Sample
2. If available, offer patient referral to survivorship program
3. Generate plan of care for any residual side-effects of cancer treatment

Surveillance Care (average risk individuals) **

Follow Up Care

Talk with your provider about reliable testing options. Discuss what screening tests and schedule are right for you.

<i>Follow Up Care</i>	<i>Recommendation</i>	<i>Coordinating Provider</i>
Medical history and physical examination	Visit your provider every three to six months for the first two years, then annually. Next appt: ***	***
Chest CT with/without contrast	Every three to six months for two years, then annually. Next appt: ***	***
Smoking status assessment	At each visit, with referral for quitting assistance if needed.	
Immunizations	Influenza, Pneumococcal, Tetanus or TDAP, other immunizations as recommended by provider	
Coordination of care	About a year after diagnosis, you may continue to visit your oncologist or transfer your care to a primary care provider.	

See Appendix 1 for Full Survivorship Care Plan Template Sample

Appendix 1 Providence Epic Survivorship Care Plan Template

2015 Revisions in review to be updated with final by 3/31



Appendix 2 Providence & Swedish Clinical Trials – Lung Cancer

Pacific Cancer Research Consortium

Contact your local research office for available trials and eligibility criteria.

Appendix 3 SBRT Equipment Inventory



SBRT Equipment
Survey Results Octot

Appendix 4 Reference Materials



0618.pdf

RTOG 0618



SBRT lung 0813.pdf

RTOG 0813



SBRT lung
0915[1].pdf

RTOG 0915