South West Wales Cancer Centre

Department of Radiotherapy: Quality System
Department of Radiotherapy Physics: Quality System

Radiotherapy Clinical Protocol: SABR Lung

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Radiotherapy technique & dose protocol: SABR Lung

Date	Doc Ref / Revision Number	Details of Change
Jan 2022	RTQW4169	New Document
Oct 2022	RTQW4169/2.0	Incorporating changes as a result of the local 'post 10 patient review' meeting
Mar 2025	RTQW4169/3.0	Document review and minor updates

Objective

This protocol outlines radiotherapy technique and dose, fractionation for patients referred for stereotactic ablative radiotherapy (SABR) for treatment of pulmonary lesions.

Scope

Any patients referred to the Department of Clinical Oncology & Radiotherapy for SABR to parenchymal lung lesions.

Responsibility

Please see RTQW4177.

Documentation

Electronic IR(ME)R booking form	RTQW1009
Prescribing Radiotherapy	RTQW3007
Oncologist/SpR/Locum IR(ME)R entitlement form	RTQF3016
Prescribing, recording and reporting photon beam therapy	ICRU Report 50
SABR WI Treatment / Imaging	RTQW4167
SABR Lung Workbook	RTQW4168
Plan of the day treatment prescription preparation	RTQW4174
Prescribing, recording and reporting photon beam therapy	ICRU Report 62
Prescribing, recording and reporting photon beam IMRT	ICRU Report 83
Prescribing, recording and reporting of stereotactic treatments with small photon beams	ICRU Report 91
Common toxicity criteria for adverse events (CTCAE) version 4	
Protocol for Radiographer Review : SABRLung	RTQW4170/1
Image Verification training and Training and Competency Workbook (2D/3D/4D)	RTQW4131
SABR Patient Information Leaflet	RTQEB1085
SABR Patient Information Leaflet (Welsh)	RTQEB1085(W)
SABR Radiographer Review Protocol	RTQW4170
4D Planning CT Scans on Philips Big Bore (CTSIM2)	RTQW2024
RTP Treatment Planning: SABR Lung	QWORK3.171
Dose Constraints: SABR Lung	QFORM3.172

Method

Background to the Role of stereotactic radiotherapy

SABR is considered standard of care for peripherally located early stage lung cancer in patients who are not fit for or decline surgery. Both international randomised trials (Ball et al 2019) and national registry data (Phillips et al 2019) have confirmed its superiority to conventionally fractionated radiotherapy demonstrating improved local control of the treated tumour and improved ove all survival. In addition it is a well-tolerated treatment with a favourable side effect profile and is suitable for patients with poor respiratory reserve thereby offering a curative treatment to a group of patients previously deemed unfit for treatment. Population data (Palma et al) has demonstrated improved survival in elderly patients following the introduction of SABR as a consequence of increasing the number of patients able to receive curative radiotherapy and reducing the proportion of patients referred for best supportive care alone.

Indications for radiotherapy/patient selection (Referral criteria)

Initial/diagnostic investigations

Initial/diagnostic investigations

- **Bloods** FBC, U&E, LFT, bone profile
- **Radiology** CXR, CT (thorax + upper abdo with contrast)
- **Histology/Biopsy** CT guided biopsy if technically feasible/PFT allow. EBUS may be required to confirm nodal staging
- **Full pulmonary Function Test (including gas transfer)**

Staging investigations

- CT/PET for all patients potentially suitable for radical/curative treatment.

Eligibility criteria for radical radiotherapy

Inclusion criteria (as per UK SABR consortium guidelines v6.1, January 2019)

- MDT diagnosis of NSCLC based on findings of positive histology or a positive PET scan when predictive models (e g. Herder, Brock) indicate a > 70% risk of malignancy.
- Clinical stages of T1 N0 M0 or T2 (≤5 cm) N0 M0 or a subset of T3 (by virtue of chest wall invasion only) (≤5 cm)
- Not suitable for surgery because of medical co-morbidity, lesion is technically inoperable or patient declines surgery after surgical assessment (or option of assessment)
- WHO performance status 0-2. Patient who are WHO PS3 due to pre-existing co-morbidites may be eligible at an individual consultant's discretion.
- Peripheral lesions, defined as outside the 'UltraCentralZone'. (figure 2)
- Age ≥ 18 years
- All patient being considered for SABR must be discussed in the SWWCC and/or VCC lung radiotherapy planning meeting to confirm suitbaility for SABR treatment.

Relative Contra-Indications

- Target motion due to respiration ≥ 1 cm despite using techniques to reduce tumour motion
- Presence of pulmonary fibrosis (consider and consent for the increased risk of significant toxicity)

Centrally located tumours

For centrally located tumours (Figure 1, not invading central structures and not ultra centrally located tumours (Fig 2), there is limited evidence for efficacy compared to more conventional fractionation. There is also limited evidence that the benefit outweighs the risk compared to more conventional fractionation. Therefore, caution should be taken when using SABR in this patient population and decisions should be made on an individual patient basis.

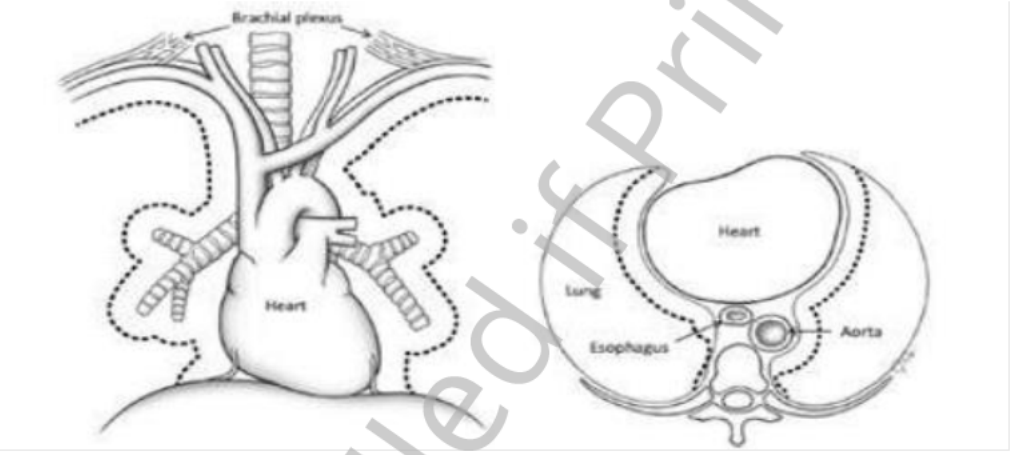

Fig 1. IASLC 'central' zone definition. Any GTV within 2 cm zone around bronchial tree, major vessels, heart, oesophagus, spinal cord, phrenic & recurrent laryngeal nerve or brachial plexus

Not eligible

Exclusion Criteria

- Any tumour that is not clinically definable on the treatment planning CT scan e.g. surrounded by consolidation or atelectasis.
- Previous radiotherapy within the planned treatment volume
- Pregnant or lactating females
- Inability to obtain informed consent or comply with treatment requirements
- For ultra-central y located lesions (Figure 2, motion adapted GTV within 1 cm of proximal bronchial tree) and tumours invading central structures (e.g. Large blood vessels, oesophagus, trachea) SABR treatment is not recommended outside of clinical trials.

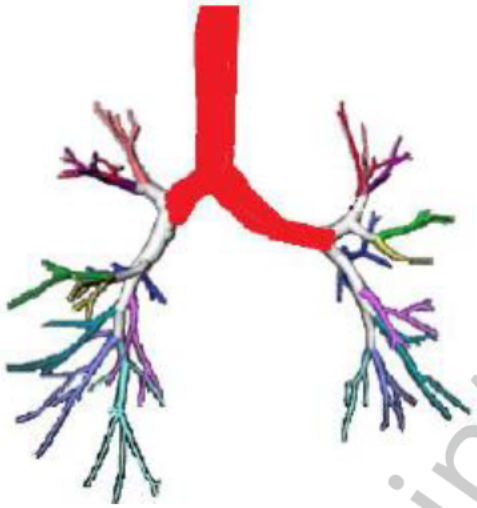

Figure 2. Nordic Hilus trial 'ultra-central' zone definition. Any GTV ≤ 1cm from the proximal bronchial tree, overlapping the trachea or main bronchi.

Treatment plan

- The intention of this treatment is curative, **this should be discussed with the patient and clearly documented on the consent form.**
- Poor respiratory reserve/lung function tests is not an exclusion criteria for SABR and there is no cut-off value for FEV1/transfer factor below which SABR cannot be given. Patients with poor lung function test values or poor exercise capacity should, however, be counselled regarding the risks of radiotherapy and consideration given to including the requirement for long term oxygen when completing the consent form.

Determination of Target Volume

4DCT planning

Accounting for the full range of tumour motion and the movement of surrounding OARs is essential, and therefore the use of 4DCT is mandatory for planning SABR to lung parenchymal tumours. It may be necessary to combine a 4DCT with a 3D scan if scan length in 4D is an issue.

For disease located within the lower third of the lung, abdominal compression may be considered if tolerated by the patient to help reduce tumour motion.

The lung SABR booking form includes a mandatory field to be filled in specifying the tumour's geographical location within the lung (zones and not lobes). The option selected will primarily guide the necessary scanning requirements in terms of routine scan length (± 3DCT in addition to routine 4DCT), as well as IV contrast usage.

Tumour volume delineation

- The Gross Tumour Volume (GTV) is marked to include all the known primary disease as identified on the diagnostic CT/PET-CT using lung window settings. Mediastinal window settings may additionally be used where tumours abut the chest wall or mediastinum.

- The average intensity projection (AVIP) of the 4DCT will be the primary dataset (used for planning), however this will be fused to the total 4DCT (± contrast enhanced 3DCT) to aid delineation
- The GTV is delineated, whilst viewing the mid-expiration phase of the 4DCT
- This structure is then copied and labelled 'motion-adapted GTV' (might be described as ITV)
- This GTV is then adjusted whilst viewing each phase of the 4D dataset and the contour expanded to account for motion. NB the structure should NOT be made smaller unless to correct for an error.
- The target volume should be visually confirmed on all respiratory phases on axial, coronal and sagittal views, by playing a cine-movie of the datasets representing different phases of the respiratory cycle to ensure all areas of disease are encompassed.
- Clinical Target Volume (CTV) is the motion adapted GTV with no margin for microscopic disease extension.
- The motion-adapted GTV (ITV) is expanded by 5 mm isotropically to create the PTV

PTV	Motion adapted GTV + 0.5 cm

Organs at risk

- Routine outlining of most organs at risk (OAR) is undertaken by Radiotherapy Physics Technologists (RTP Technologists) as indicated in the 'SABR Lung Treatment Planning WI' (QWORK3.171).
- OARs will be outlined on the generated AVIP dataset
- The clinician is responsible for outlining any OAR not routinely undertaken by the RTP Technologists. This includes Brachial Plexus, Proximal Bronchial Tree (+ subsequent 'UltraCentralZone'), Great Vessels and Proximal Trachea.
- For thoracic SABR, critical organs (Lungs, spinal canal, heart, Oesophagus, proximal bronchial tree, proximal trachea, ipsilateral brachial plexus for upper zone, liver/spleen for lower zone tumours) should be outlined to enable Dose Volume Histograms (DVHs) to be constructed.
- **If the motion-adapted GTV overlaps with the 'UltraCentralZone' then this cannot be treated with SABR.**
- Checking the DVHs to ensure they meet the dose constraints specified in 'Dose Constraints: SABR Lung' (QFORM3.172) must be undertaken before approving any plan

Treatment modality

6FFF photon VMAT plan will be used for all patients.

Field arrangement

- Appropriate arcs will be selected to cover the target volume and to meet the dose constraints specified in the 'SABR Lung Treatment Planning WI' (QWORK3.171).

Dose and fractionation

For peripherally located lesions, there is strong evidence that SABR is superior to conventional radiotherapy for efficacy and safety with substantial clinical benefit. The two recommended dose fractionation schedules are:

- 54 Gy in 3 fractions. *'Standard' fractionation*. Schedule for PTV not abutting chest wall.
- 55 Gy in 5 fractions. *'Conservative' fractionation*. Schedule for PTV abutting or overlapping chest wall.
- It is recommended that this is an alternate day treatment however a minimum of 24 hours is required between fractions, with a maximum interval of ideally 4 days between fractions.

If SABR is being used, for centrally located tumours (Figure 2), the recommended schedule is:

- 60 Gy in 8 fractions. *'Ultra-conservative' fractionation*. Schedule for centrally located motion adapted GTV, but outside ultra-central zone.
- For ultra-centrally located lesions (Figure 2, motion adapted GTV within 1 cm of proximal bronchial tree) and tumours invading central structures (e.g. Large blood vessels, oesophagus, trachea) SABR treatment is **not** recommended outside of clinical trials. Conventional or moderately hypo-fractionated (e.g. 55 Gy in 20 fractions) have been used safely in locally advanced NSCLC therefore should be safe in early stage ultra-centrally located NSCLC.
- For individual plans, that are exceeding Heart+A_Pulm dose constraint tolerance, consider reducing prescription dose from '60 Gy in 8 fractions' to '50 Gy in 8 fractions'.

Organs at risk

The following guidance for superior and inferior lengths of contours required, are with the assumption of coplanar treatment arc/field delivery. If non-coplanar arcs/fields are used, then further extension of structure contouring (± 10 cm) is advised.

Spinal Canal

- A contour based on the bony limits of the spinal canal, ≥2cm superior and inferior of the PTV, will sufficiently allow for a conservative estimate of spinal cord dose.
- An isotropic margin of 3 mm will be added to create 'SpinalCanal_PRV'.

BrachialPlex_L (or) BrachialPlex_R

- The defined ipsilateral brachial plexus originates from the spinal nerves exiting the neural foramina on the involved side from around C5 to T2. However, for the purposes of this guide only the major trunks of the brachial plexus will be contoured using the subclavian and axillary vessels as a surrogate for identifying the location of the brachial plexus.
- This neurovascular complex will be contoured starting proximally at the bifurcation of the brachiocephalic trunk into the jugular/subclavian veins (or carotid/subclavian arteries), and

following along the route of the subclavian vein to the axillary vein ending after the neurovascular structures cross the 2nd rib. Use of contrast at CT may assist with outlining.

- An isotropic margin of 3 mm will be added to create 'BrachialPlex_PRV'

Oesophagus

- The entire oesophagus will be contoured using mediastinal windowing on CT to correspond to the mucosal, submucosa, and all muscular layers out to the fatty adventitia.
- An isotropic margin of 3 mm will be added to create 'Oesophagus_PRV'

Heart+A_Pulm

- The heart will be contoured along with the pericardial sac. The superior aspect (or base) for purposes of contouring is defined as the superior aspect of pulmonary artery (as seen in a coronal reconstruction of the CT scan) and extended inferiorly to the apex of the heart.
- An isotropic margin of 3 mm will be added to create 'Heart+A_Pulm_PRV'

Trachea and proximal bronchial tree

- The trachea and proximal bronchial tree can be contoured either as a single structure or as two separate structures using lung windows. For this purpose, the trachea can be divided into two sections: the proximal trachea and the distal 2 cm of trachea.
- The proximal trachea will be contoured as one structure, and the distal 2 cm of trachea will be included in the structure identified as proximal bronchial tree.
- Differentiating these structures in this fashion will facilitate the eligibility requirement for excluding patients with tumours within the 'UltraCentralZone' and appropriate dose fractionation selection.

Trachea_Prox

- Proximal trachea. Contours should begin 2 cm superior to superior extent of PTV and continue inferiorly to the superior aspect of the proximal bronchial tree.
- An isotropic ma gin of 3 mm will be added to create 'Trachea_Prox_PRV'.

Bronchus_Prox

- Proximal bronchial tree. This will include the most inferior distal 2 cm of trachea and the proximal airways on both sides.
- The following airways will be included: distal 2 cm trachea, carina, right and left mainstem bronchi, right and left upper lobe bronchi, the bronchus intermedius, right middle lobe bronchus, lingular bronchus, and the right and left lower lobe bronchi. Contouring of the lobar bronchi will end immediately at the site of a segmental bifurcation.
- '**UltraCentralZone**' is created from 'Bronchus_Prox' + 1cm isotropically.
- An isotropic margin of 3 mm will be added to create 'Bronchus_Prox_PRV'.

GreatVes

- The great vessels (aorta and vena cava, not the pulmonary artery or vein) will be contoured using mediastinal window to correspond to the vascular wall and all muscular layers out to the fatty

adventitia. The great vessel should be contoured at least 2 cm above and below the extent of the PTV.

- For right sided lesions, the vena cava will be contoured,
- For left sided lesions, the aorta will be contoured

- An isotropic margin of 3 mm will be added to create 'GreatVes_PRV'.

Whole lung

- Both lungs should be contoured from apex to base as one structure using pulmonary windows. All inflated and collapsed lung should be included.
- ITV and trachea/ipsilateral bronchus as defined above should not be included.

Chest wall (for peripheral lesions)

- The chest wall will be defined as the 2 cm rind of the ipsilateral hemi-thorax outside the lungs and contoured at least 2 cm superiorly and inferiorly to the PTV. Includes ribs, intercostal vessels, nerves and muscles, and excludes vertebral bodies, ste num, and skin.

Liver

- For right lower zone tumours the whole liver should be outlined, excluding the gall bladder and hepatic vessels.
- Where the whole liver is not included in the planning CT scan the dose-volume reported will provide a conservative estimate of the dose constraint.

Spleen

- For lower zone tumours, the whole Spleen should be outlined.

Skin

- Defined as a 5 mm inner rind of body contour contoured if adjacent to PTV and in regions receiving more than 10Gy.

Dose constraints

Please see QFORM3.172

Treatment verification

- Daily on-line CBCT is mandatory for all patients receiving SABR to facilitate tumour matching and accurate dose delivery see imaging protocol, see RTQW4131 for more information. Surface Guided Radiotherapy SGRT, will also be used to verify treatment position / set up each fraction and to monitor the patient surface during treatment delivery. See RTQW4164 for more information.
- Consideration may be given to undertaking a 'day zero' if any of the conditions listed below are observed. This may be finalised in the SABR MDT meeting on an individual patient basis:
  - set up problems are anticipated
  - tumour motion >10mm is observed within the planning CT scan
  - Inconsistency in patient breathing trace is highlighted during planning CT scan

- Patients will be imaged using 3DCBCT or 4DCBCT. 3DCBCT can be utilised if 4DCBCT unavailable or where clinically indicated see RTQW4167 for more information
- Patients in radiotherapy trials will be imaged according to trial protocol; it is the responsibility of the Clinical Oncologist acting as Principal Investigator to check that any trial imaging requirements meet with the departmental imaging strategy. Any additional imaging dose required for the trial is to be justified (in the IR(ME)R sense).

Thoracic Reirradiation

Depending on the clinical situation each patient should be carefully considered for reirradiation and any potential risk of excessive toxicity to normal tissue be discussed with the patient and should be justified clinically. It is advised to review these patients in the lung planning meeting for discussion and peer review.

On-treatment review

Patients receiving a course of SABR for lung cancer may be seen or contacted by the review radiographers before, during and for 24 months post radiotherapy. Please refer to RTQW4170.

Follow up arrangements

For patients suitable for further active oncological treatment, the follow up schedule described below may be considered:

- Use of CTCAE v5.0 is recommended for assessing toxicity during and after RT.
- Following lung SABR the first follow up should is recommended to take place at 4-6 weeks post radiotherapy to assess acute toxicity.
- CXR imaging should be requested where there are clinical concerns of pneumonitis.
- Subsequent follow up visits should be of the order of 3 monthly for the 1st year, and 6 monthly for subsequent yea s.
- Consideration should be given to collecting quality of life data if possible which can be facilitated via PROMS where available.
- First post treatment CT scan should be done at 3-4 months and then repeated at least every 3-12 months depending on circumstances.
- Due attention must be given to the difficulty that can arise in differentiating local recurrence from tumour progression in certain scenarios
- In addition, a greater awareness of the potential for certain toxicities (e.g. chest wall/rib) is required.
- If feasible full lung function tests should be considered annually.
- Response may be documented using the RECIST criteria.
- Ideally, patients should be followed for a minimum of five years.

Dose modification

- Inclusion/exclusion criteria must be strictly adhered to as defined above to determine the appropriate dose/fractionation schedule depending on tumour location within the thorax.
- Dose modification/compromise may be required to respect OAR dose constraints e.g. for lesions close to or abutting vertebrae. This must be approved by the responsible consultant at plan review.

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