NHS Commissioning Board

Clinical Commissioning Policy: Stereotactic Ablative Body Radiotherapy for Non-Small-Cell Lung Cancer (Adult)

April 2013

Reference: NHSCB/B01/P/a

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Clinical Commissioning Policy: Stereotactic Ablative Body Radiotherapy for Non-Small-Cell Lung Cancer (Adult)

First published: April 2013

Prepared by the NHS Commissioning Board Clinical Reference Group for Radiotherapy

First published April 2013
Published by the NHS Commissioning Board, in electronic format only.

Contents

Policy Statement

The NHS Commissioning Board (NHS CB) will commission Stereotactic Body Radiotherapy / Stereotactic Ablative Radiotherapy for a small subset of patients with early non small cell lung cancer within defined criteria in accordance with the criteria outlined in this document. There is currently insufficient evidence to support the routine commissioning of SBRT/SABR in other indications

In creating this policy the NHS CB has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population in England.

Equality Statement

The NHS CB has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012.The NHS CB is committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation. In carrying out its functions, the NHS CB will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which they are responsible, including policy development, review and implementation.

Plain Language Summary

Lung cancer is responsible for 1 in 7 new cases of cancer and approximately 4 of 5 patients with lung cancer have non-small cell lung cancer (NSCLC). Of this group, 1 in 5 has early-stage disease which is associated with the best chance of cure. Lung cancer is more common in elderly patients and smokers, who have a higher incidence of other medical conditions. This means that in a proportion of patients with early stage NSCLC, surgery is too risky. Such patients are termed ‘medically inoperable’. Some other patients may be inoperable for technical reasons.

Stereotactic body radiotherapy refers to the use of highly targeted radiation therapy to structures outside the brain and skull.

The only indication for the use of stereotactic body radiotherapy that is currently supported by scientific evidence is as a treatment option for early stage non small cell lung cancer.

Patients who meet the clinical criteria outlined in this policy who are not suitable for surgery are eligible for this treatment.

1. Introduction

Stereotactic body radiotherapy (SBRT/ SABR) refers to the precise irradiation of an image defined extra cranial lesion and is associated with the use of a high radiation dose delivered in a small number of fractions. The technique requires specialist positioning equipment and imaging to confirm correct targeting. It allows sparing of the surrounding healthy normal tissues.

For the purpose of this policy the SBRT/ SABR refers to hypofractionated treatment of not more than 8 fractions. Commissioning arrangements for fractionated treatments utilising a larger number of fractions are beyond the remit of this policy.

This policy concerns the use of SBRT/SABR in extra-cranial malignant disease. However, the only indication that is currently supported by evidence is as a treatment option for early stage non small cell lung cancer.

2. Definitions

Stereotactic body radiotherapy (SBRT)

Stereotactic radiation therapy has been used for benign and malignant lesions in the brain for many years. Stereotactic radiosurgery (SRS) is a single fraction of stereotactic directed radiation of a limited volume in the brain or other structure of the skull base, whereas stereotactic radiotherapy (SRT) has been defined as a fractionated stereotactic directed radiation of a limited volume in the brain. Stereotactic body radiotherapy (SBRT / SABR) refers to the use of stereotactically directed radiation therapy to structures outside the brain and skull.

Extra-cranial malignant disease

Extra-cranial malignant disease is a catch all term for all malignancies excluding cerebral metastases which is the subject of a separate policy.

Non Small Cell Lung Cancer (NSCLC)

Lung cancer is responsible for 1 in 7 new cases of cancer and is responsible for 22% of all cancer deaths. Approximately 80% of patients have non-small cell lung cancer (NSCLC), of whom about 20% have early-stage disease (AJCC Stage I, TNM Stage T1-2N0M0) which is associated with the best chance of cure. Lung cancer is more common in elderly patients and smokers, who have a higher incidence of medical co-morbidity. This means that in a proportion of patients with early stage NSCLC, surgery is too risky. Such patients are termed ‘medically inoperable’. Some other patients may be inoperable for technical reasons.

World Health Organisation (WHO) performance status

The WHO performance scale is one way of assessing general health. The WHO performance status classification categorises patients as:

- 0: able to carry out all normal activity without restriction
- 1: restricted in strenuous activity but ambulatory and able to carry out light work
- 2: ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours
- 3: symptomatic and in a chair or in bed for greater than 50% of the day but not bedridden
- 4: completely disabled; cannot carry out any self-care; totally confined to bed or chair.

TNM

The TNM system is one of the most widely used staging systems for cancer. This system has been accepted by the International Union Against Cancer (UICC) and the American Joint Committee on Cancer (AJCC).

The TNM system is based on the extent of the tumour **(T)**, the extent of spread to the lymph nodes **(N)**, and the presence of distant metastasis **(M)**. A number is added to each letter to indicate the size or extent of the primary tumour and the extent of cancer spread.

3. Aim and Objectives

To identify whether there is sufficient robust evidence of clinical and cost-effectiveness and safety to support the use of SBRT / SABR in extra-cranial malignant disease. If so, for which malignancies.

To identify whether the evidence is sufficiently robust, what criteria should be used to identify suitable patients to be considered for SBRT/ SABR.

4. Criteria for commissioning

Patients meeting all the following criteria will be routinely funded for SBRT / SABR:

- Multidisciplinary Team (MDT) confirmed diagnosis of NSCLC based on findings of positive histology, positive PET scan or growth on serial CT scan **AND**
- Clinical stages of: T1 N0 M0
  T2 (≤5cm) N0 M0
  T3 (≤5cm) N0 M0 **AND**
- Not suitable for surgery because of medical co-morbidity or lesion is technically inoperable **AND**
- WHO performance status 0-2 **AND**
- Peripheral lesions outside a 2cm radius of main airways and proximal bronchial tree. This is defined as 2cm from the bifurcation of the second order bronchus e.g. where the right upper lobe bronchus splits

Exclusion criteria

- Any tumour not clinically definable on treatment planning CT scan e.g. surrounded by consolidation or atelectasis
- Significant overlap with previous radiotherapy fields
- Advanced interstitial lung disease

5. Patient pathway

The service specification for radiotherapy describes the detail of the care pathways and describes the key aspects of SBRT / SABR services being commissioned and should be referred to in conjunction with this policy.

The alternative treatment option for Stage 1 NSCLC is surgical resection.

6. Governance arrangements

The service specification for SBRT / SABR describes the governance arrangements for this service.

In particular doses of up to 60Gy in up to 8 fractions should be used as per UK SABR guidelines.

7. Epidemiology and needs assessment

Lung cancer is responsible for 1 in 7 new cases of cancer and is responsible for 22% of all cancer deaths. Approximately 80% of patients have non-small cell lung cancer (NSCLC), of whom about 20% have early-stage disease (AJCC Stage I, TNM Stage T1-2N0M0) which is associated with the best chance of cure. Lung cancer is more common in elderly patients and smokers, who have a higher incidence of medical co-morbidity. This means that in a proportion of patients with early stage NSCLC, surgery is too risky. Such patients are termed 'medically inoperable'. Some other patients may be inoperable for technical reasons.

Lung Cancer incidence is 32,000 cases per year in England. If all early stage operable NSCL cancers were to have SBRT / SABR, there are potentially 11,000 cases per year. If all early stage medically inoperable NSCLC cases, and applying data from 2009 LUCADA audit, there are potentially 3,000 cases. Cautious estimates assuming approximately one-third of such cases, suggests there may be circa 1,000 cases per year.

8. Evidence Base

There is now considerable non-randomised evidence supporting SBRT/SABR as superior to conventional RT with respect to local control and survival. This is biologically plausible. Lung SBRT/SABR also appears to have an acceptable therapeutic index as the toxicity of this technique is relatively low when treating T1-2 tumours in the periphery of the lung. Table 1 lists the RT regimen, control rates and toxicity seen in studies in which more than 40 patients were treated and more detailed summary of the clinical data has been published by Chi et.al. (2010). De Reysscher et.al have also reviewed the literature and have graded their recommendations for the implementation of SBRT / SABR in early lung cancer.

Table 1 Summary of outcome and toxicity of SBRT / SABR in studies (n >40)

Study	Patient Nos	Schedule	BED (α/β = 10)	Median FU (months)	Actuarial local control	Survival	Complications
Baumann et al, 2006	138	30-48 Gy in 2-4 #	60-120 Gy	33	85% (3 yr)	52% (3 yr) 26% (5 yr)	Atelectasis >Grade 2 (2%); Pneumonitis >Grade 2 (1%); Rib fractures (4%)
Lagerwaard et al, 2007	197	3 x 20Gy 5 x 12 Gy	180 Gy 132 Gy	12	94% (2 yr)	64% (2 yr)	Pneumonitis >Grade 2 (3%); Rib fractures (2%)
Nagata et al, 2005	45	4 x 12 Gy	106 Gy	30	98% (2 yr)	72% (3 yr)	Pneumonitis >Grade 2 (0%)
Nyman et al, 2006	45	3 x 15 Gy	113 Gy	43	80% (crude)	55% (3 yr)	Pneumonitis >Grade 2 (0%); Rib fractures (4%)
Onishi et al, 2007	257	18-75 Gy in 1-22 #	Miscell-aneous	38	84% (5 yr BED>100) 37% (5 yr BED<100)	71% (5 yr) 30% (5 yr)	Pneumonitis >Grade 2 (5%)

9. Rationale behind the policy statement

The evidence regarding the effectiveness and safety of SBRT / SABR for treating extra-cranial malignancy has been used as a basis for this commissioning policy.

The CRG has not updated the literature review since the National Radiotherapy Implementation Group report of 2011.

There is sufficient evidence to routinely commission SBRT for a small subset of patients with early non small cell lung cancer meeting explicit inclusion and exclusion criteria.

All other uses of SBRT / SABR to treat extra-cranial malignancies should only be used within the context of a clinical trial.

10. Mechanism for funding

Through the relevant Area Team.

11. Audit Requirements

Providers will be expected to provide information on activity and outcomes on request.

12. Documents which have informed this policy

National Radiotherapy Implementation Group Report. Stereotactic Body Radiotherapy Guidelines for Commissioners, Providers and Clinicians in England 2011. Available from: http://www.ncat.nhs.uk/sites/default/files/NRIG%20SBRT%20Final%20June%2011.pdf. Accessed September 2012.

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13. Links to other policies

- Approaches to experimental treatments
- Individual funding request (IFR) process
- Stereotactic radiosurgery/stereotactic radiotherapy for cerebral metastases

14. Date of Review

April 2014

Change Notice for Published Specifications and Products

developed by Clinical Reference Groups

Amendment **to the Published Products**

Product Name	Clinical Commissioning Policy: Stereotactic Ablative Body Radiotherapy for Non- Small- Cell Lung cancer (Adults)
Ref No	B01/P/a
Programme of Care Lead	Radiotherapy

Description of changes required

Describe what was stated in original document	Describe new text in the document	Section/Paragraph to which changes apply	Describe why document change required	Changes made by	Date change made
Stereotactic Body Radiotherapy/Stereotactic Ablative Radiotherapy	Stereotactic Ablative Body Radiotherapy for Non- Small-Cell Lung Cancer (Adults)	Title page and second page	To standardise naming and coding of products	Cancer and Blood National Programme of Care Director	August 2013