NHS England

Clinical Commissioning Policy Proposition:

The use of Stereotactic Ablative Radiotherapy (SABR) in the treatment of previously irradiated tumours of the pelvis, spine and nasopharynx

Reference: NHS England B01X15

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1 Executive Summary

Policy Statement

NHS England proposes to not routinely commission Stereotactic Ablative Radiotherapy in the treatment of previously irradiated tumours of the pelvis, spine and nasopharynx.

In creating this policy proposition NHS England has reviewed a number of clinical conditions and the options for 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.

Equality Statement

NHS England 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. NHS England is committed to fulfilling this duty as to equality of access and to avoiding unlawful discrimination on the grounds of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, gender or sexual orientation. In carrying out its functions, NHS England 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 NHS England is responsible, including policy development, review and implementation.

Plain Language Summary

The policy proposition aims to confirm NHS England's commissioning approach to the use of Stereotactic Ablative Radiotherapy (SABR) as a treatment option in the treatment of previously irradiated tumours of the pelvis, spine and nasopharynx.

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

2 Introduction

This document describes the evidence that has been considered by NHS England in formulating a proposal to not routinely commission Stereotactic Ablative Radiotherapy in the treatment of previously irradiated tumours of the pelvis, spine and nasopharynx.
For the purpose of consultation NHS England invites views on the evidence and other information that has been taken into account as described in this policy proposition.
A final decision as to whether NHS England will continue to routinely commission SABR as a treatment for previously irradiated tumours of the pelvis, spine and nasopharynx is planned to be made by NHS England by May 2016 following a recommendation from the Clinical Priorities Advisory Group.

3 Proposed Intervention and Clinical Indication

For the purpose of this policy SABR refers to hypo-fractionated 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 SABR in the treatment of previously irradiated tumours of the pelvis, spine and nasopharynx.

4 Definitions

Stereotactic body radiotherapy (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.

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 Ablative radiotherapy (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.

Previously irradiated tumours of the pelvis, spine and nasopharynx

Various tumours may arise in the pelvis, spine and nasopharynx. Pelvic tumours include colo-rectal, prostatic and gynaecological carcinomas, all of which may metastasise to regional lymph nodes. Spinal tumours are often metastases, and nasopharyngeal carcinomas may not be cured by initial treatment or may recur locally.

After initial treatment, which may include surgery, radiotherapy and/or chemotherapy, recurrences and metastases from these tumours may be treated with SABR.

5 Aims and Objectives

This policy proposition considered:

Whether there is sufficient robust evidence of clinical and cost- effectiveness and safety to support the use of SBRT / SABR in the treatment of patients with previously irradiated tumours of the pelvis, spine and nasopharynx.
The objectives were to:

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

6 Epidemiology and Needs Assessment

No randomised trials or systematic reviews were identified in relation to the treatment of patients with previously irradiated tumours of the pelvis, spine and nasopharynx with SABR. A summary of the evidence by tumour type is as follows:

6.1. Spinal tumours

Two uncontrolled studies were identified:

- Garg et al (2011) reported a series of participants with spinal metastases which had previously been treated with external beam radiotherapy.They reported one-year local progression-free survival of 76% and median overall survival of 22.5 months. The patients also reported pain relief after SABR, though this result was not clearly described.

- Participants in Sahgal et al's (2009) study also had spinal metastases, some of which had previously been irradiated. The results for those with and without previous irradiation were not reported separately, but were not significantly different. The overall median survival was 21 months, and one-year and two-year progression-free survival rates were 85% and 69% respectively.

6.2 Pelvic tumours

Two uncontrolled studies were identified:

- Abusaris et al (2012) reported results from 27 people with abdominal and pelvic tumours which had previously been irradiated.Twenty-one of the twenty-seven recurrences were pelvic, and rectal cancer was the commonest primary.

Pelvic recurrences were not separately reported. Local control rates were 64% at one year and 53% at two years. Overall survival rates were 52% and 37% respectively, and median overall survival was 14 months.

- Dewas et al's (2011) series was of 16 people with recurrent carcinoma in the lateral pelvis. They reported median disease-free survival of 8.3 months and median overall survival of 11.5 months. One-year survival was 46%.

6.3 Nasopharyngeal tumours

Two controlled studies were identified:

- Chua et al (2009) treated 74 people with previously irradiated, persistent or recurrent nasopharyngeal cancer with either SABR or brachytherapy from radioactive gold grains. The study was unrandomised, but the authors aimed to match participants in the two arms for variables that might influence their prognosis.

Rates of local treatment failure and overall survival were similar in the two arms of Chua et al's (2009) study. The study was small and lacked a power calculation, so may have been underpowered.

- The second controlled study was by Ozyigit et al (2011). Participants with recurrent nasopharyngeal carcinoma treated before June 2007 had conformal radiotherapy, while after that date they had SABR. The study was small and reported similar two-year local control and cancer-specific survival after the two treatments. It may also have been underpowered.

A further nine uncontrolled studies were identified. Studies with fewer than a hundred participants were excluded as inclusion would have not provided any further information on the effectiveness of SABR relative to other treatments. This left one study for inclusion in relation to this policy:

- Liu et al (2013) reported on 136 people who had residual disease after conventional radiotherapy. Overall survival after three years was 86%, and after five years was 76%. Disease-free survival rates were 79% and 74% respectively.

- Chua et al (2009) reported on people treated with fractionated or unfractionated SABR for nasopharyngeal carcinomas in which previous radiotherapy had not been fully successful. Local control was better after fractionated SABR, perhaps because the dose was higher, but survival was similar.

7. Evidence Base

The evidence regarding the effectiveness and safety of SBRT / SABR for treating patients with previously irradiated tumours of the pelvis, spine and nasopharynx has

been used as a basis for this commissioning policy. The evidence base indicates that there is insufficient evidence to routinely commission SBRT for this cohort of patients.
This policy will replace the current published clinical commissioning policy statement on this topic.

NHS England commissioned an evidence review (Solutions for Public Health, 2015) in relation to the clinical indication outlined in this policy.

8. Documents That Have Informed This Policy Proposition

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.

National Radiotherapy Implementation Group Report. Stereotactic Body Radiotherapy Clinical review of the evidence for SBRT 2011.

Yorkshire and the Humber commissioning policy
Stereotactic radiosurgery/radiotherapy.

9 Date of Review

This document will lapse upon publication by NHS England of a clinical commissioning policy for the proposed intervention that confirms whether it is routinely or non-routinely commissioned (expected by May 2016).

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Previously irradiated tumours of the pelvis, spine and nasopharynx

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