NHS England

Clinical Commissioning Policy: The use of Stereotactic ablative radiotherapy (SABR) in the treatment of previously irradiated tumours of the pelvis, spine and nasopharynx

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

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Contents

Policy Statement

NHS England will not routinely commission the use of Stereotactic Ablative Radiotherapy (SABR) in the treatment of previously irradiated tumours of the pelvis, spine and nasopharynx in accordance with the criteria outlined in this document. In creating this policy NHS England 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

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

Plain Language Summary

The proposal aims to confirm NHS England's approach to the use of Stereotactic Ablative Radiotherapy (SABR) as a treatment option for tumours of the pelvis, spine and nasopharynx which have already been treated with conventional, or standard, radiotherapy. The nasopharynx is the area which links the nose to the throat.

About SABR treatment

Stereotactic Ablative Radiotherapy (SABR) is a highly targeted radiation therapy which aims to target a tumour with radiation beams from different angles at the same time so that:

- The tumour receives a high dose of radiation
- The tissues around the tumour receive a low dose

There are usually between 1 and 8 treatments, which are called ‘fractions’.

What we have decided

NHS England has carefully reviewed the evidence to treat tumours of the pelvis, spine and nasopharynx with Stereotactic Ablative Radiotherapy (SABR). We have concluded that there is not enough evidence to make the treatment available at this time.

1 Introduction

This document describes the evidence that has been considered by NHS England in formulating a proposal to not routinely commission Stereotactic Ablative Radiotherapy (SABR) in the treatment of previously irradiated tumours of the pelvis, spine and nasopharynx. For the purpose of this policy Stereotactic Ablative Radiotherapy (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

2 Definitions

Stereotactic Ablative 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.

3 Aims and Objectives

This policy considers whether there is sufficient robust evidence of clinical and cost-effectiveness and safety to support the use of Stereotactic Ablative Radiotherapy (SABR) in the treatment of patients with previously irradiated tumours of the pelvis, spine and nasopharynx.

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

4 Epidemiology and Needs Assessment

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 Stereotactic Ablative Radiotherapy (SABR).

5 Evidence Base

The evidence regarding the effectiveness and safety of Stereotactic Ablative Radiotherapy (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.

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:

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.

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%.

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 non-randomised, 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.

6 Documents which have informed this Policy

National Cancer Action Team. National Radiotherapy Implementation Group Report Stereotactic Body Radiotherapy Guidelines for Commissioners, Providers and Clinicians in England
2011. Available from: Accessed September 2012.

National Cancer Action Team. National Radiotherapy Implementation Group Report Stereotactic Body Radiotherapy Clinical Review of the Evidence for SBRT 2011.

Yorkshire and the Humber Specialised Commissioning Group. Commissioning Policy Stereotactic radiosurgery/radiotherapy.

7 Date of Review

This document will be reviewed when information is received which indicates that the policy requires revision.

References

Abusaris H, Hoogeman M, Nuyttens JJ. Re-irradiation: outcome, cumulative dose and toxicity in patients retreated with stereotactic radiotherapy in the abdominal or pelvic region. *Technol Cancer Res Treat* 2012; 11: 591-7.

Chua DT, Wei WI, Sham JS, et al. Stereotactic radiosurgery versus gold grain implantation in salvaging local failures of nasopharyngeal carcinoma. *Int J Radiat Oncol Biol Phys* 2007; 69:469-74.

Chua DTT, Wu SX, Lee V, Tsang J. Comparison of single versus fractionated dose of stereotactic radiotherapy for salvaging local failures of nasopharyngeal carcinoma: a matched-cohort analysis. *Head Neck Oncol* 2009; 1: 13-23.

Dewas S, Bibault JE, Mirabel X, et al. Robotic image-guided reirradiation of lateral pelvic recurrences: preliminary results. *Radiat Oncol* 2011; 6: 77.

Garg AK, Wang X-S, Shiu AS, et al. Prospective evaluation of spinal reirradiation by using stereotactic body radiation therapy. *Cancer* 2011; 117: 3509-16.

Liu F, Xiao JP, Xu GZ, et al. Fractionated stereotactic radiotherapy for 136 patients with locally residual nasopharyngeal carcinoma. *Radiat Oncol* 2013; 8: 157-66.

Ozyigit G, Cengiz M, Yazici G, et al. A retrospective comparison of robotic stereotactic body radiotherapy and three-dimensional conformal radiotherapy for the reirradiation of locally recurrent nasopharyngeal carcinoma. *Int J Radiat Oncol Biol Phys* 2011; 81: e263-8.

Sahgal A, Ames C, Chou D, et al. Stereotactic body radiotherapy is effective salvage therapy for patients with prior radiation of spinal metastases. *Int J Radiat Oncol Biol Phys* 2009; 74: 723-31.