NHS England

Clinical Commissioning Policy Proposition:

The use of Stereotactic Ablative Radiotherapy (SABR) as a treatment option in the management of patients with Spinal Tumours

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Policy Statement

NHS England proposes to routinely commission Stereotactic Ablative Radiotherapy in the treatment of patients with spinal meningiomas and schwannomas in accordance with the criteria outlined in this document. The evidence considered by NHS England in formulating this proposal does not support the routine commissioning of spinal arteriovenous malformations.

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

management of patients with spinal tumours in accordance with the defined eligibility criteria.

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 routinely commission Stereotactic Ablative Radiotherapy in the treatment of spinal meningiomas and schwannomas only. The evidence considered by NHS England in formulating this proposal does not support the routine commissioning of spinal arteriovenous malformations.

This document also describes the proposed criteria for commissioning, proposed governance arrangements and proposed funding mechanisms.

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 routinely commission SABR as an option in the treatment of spinal meningiomas and schwannomas 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.

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.

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 extra-cranial spinal tumours. If evidence exists to define which clinical indications this applies to.

The objectives were to:

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

6 Epidemiology and Needs Assessment

This policy document covers spinal arteriovenous malformations, meningiomas and schwannomas. These are described below:

Arteriovenous malformations (AVMs) are abnormal connections between arteries and veins. These vascular anomalies usually arise in the central nervous system, but can appear in any location. Although many AVMs are asymptomatic, they can cause pain, haemorrhage or focal neurological symptoms. The haemorrhage can be fatal.

Meningiomas are tumours arising from the meninges, the membranous layers surrounding the central nervous system. Most are benign, and many are asymptomatic. They can however cause seizures and focal neurological symptoms.

Schwannomas are tumours of the nerve sheath which produces the insulating myelin that covers peripheral nerves. They are usually benign but can produce symptoms from nerve compression.

All three of these lesions are usually treated surgically, but this can be difficult in surgically inaccessible sites or those near critical structures.

Evidence Base

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

1. What is the clinical effectiveness of stereotactic ablative body radiotherapy for spinal arteriovenous malformations, meningiomas and schwannomas which are considered not suitable for surgery (because of medical co-morbidity or because lesion is inoperable), compared to best standard care?

2. What is the cost effectiveness of stereotactic ablative body radiotherapy for spinal arteriovenous malformations, meningiomas and schwannomas which are considered not suitable for surgery (because of medical co-morbidity or because lesion is inoperable), compared to best standard care?

There were no systematic reviews and no randomised trials identified.

Seven uncontrolled studies, none of which included participants with AVMs were identified, studies with fewer than ten participants with the indications covered by this review, with respectively seven, two and one relevant participants were excluded as including these very small uncontrolled studies would have not provided any further information on the effectiveness of SABR relative to other treatments. This left four studies for inclusion in the review:

- Gerstzen et al (2008) published a case series of patients with benign spinal tumours treated with SABR. They included 35 participants with schwannoma and 13 with meningiomas, with median follow-up of 37 months. The authors do not report overall or progression-free survival, though these measures are less important for benign tumours. They report that none of the participants with meningiomas progressed during follow-up. The results for participants with schwannoma were reported according to the indication for treatment. Most of those being treated for pain experienced a reduction on pain level that the authors deemed significant.

- The same research group published results on a later set of patients (Gerszten 2008).The authors report that there was no sub-acute or long-term spinal cord or cauda equina toxicity, nor evidence of tumour growth on serial imaging. Again, they do not report overall or progression-free survival.

- Sachdev et al (2011) reported a series of 87 participants, of whom 32 had a meningioma and 47 a schwannoma. About half of the meningiomas and schwannomas reduced in size after treatment, with the others nearly all stable. The authors also report improvements in clinical state and pain, but do not describe how these were measured.

- Gagnon et al (2009) studied pain and quality of life after SABR for benign

and malignant spinal tumours. Only five of the two hundred participants in this study had meningioma, and only six had schwannomas. The authors do not report results according to the type of tumour. Overall, SABR was followed by improvements in pain which began within a month and continued throughout follow-up, a median period of one year.

The evidence review indicates that there is sufficient evidence to routinely commission SABR to treat spinal meningiomas and schwannomas (excluding) arteriovenous malformations using specific inclusion criteria.

Proposed Criteria for Commissioning

NHS England proposes to routinely commission Stereotactic Ablative Radiotherapy in the treatment of patients with spinal meningiomas and schwannomas (excluding spinal Arteriovenous malformations) in accordance with the following criteria:

Microsurgery is the first line treatment option of choice. All patients being considered for SABR must have undergone prior assessment by the local brain & CNS tumours multi-disciplinary team (MDT), who should take into consideration the patients comorbidities, likely outcome of treatment and life expectancy.

Conventionally fractionated RT versus SABR should be specifically discussed as an option in the neurosciences MDT

Then discussion in an SRS/T MDTM with spinal neurosurgeons and neuro-oncologists present. Treatment should take place in a commissioned tier1 / 2 SRS/T centre with appropriate equipment and expertise to deliver both SABR and SRS/T and be delivered by a neuro-oncologist (or neurosurgeon) who is a member of the SRS/T MDT and the spinal cord tumours MDT

Inclusion Criteria

- Tumour deemed inoperable by the MDT; AND
- Patients with sub-total resection who on surveillance later develop progressive disease after resection and for whom repeat surgical resection is deemed too high-risk or unlikely to succeed; OR
- Patients with complete resection who later develop recurrent disease after surgery for whom repeat surgical resection is deemed too high-risk; OR
- Tumour is expected to result in morbidity OR mortality without treatment; AND
- The disease process must be focal (unifocal or multifocal, that is one or few nodules, but not diffusely infiltrative); AND
- Decision to treat is shared with patient; AND
- Within volume limits deemed safely and effectively treated by SABR.

Exclusion criteria

- Patients who have previously tried and failed SRS; OR
- Operable tumours; OR
- Stable tumours without progressive symptoms or progressive growth as assessed by serial imaging; OR
- Larger or diffuse lesions more effectively treated with conventional fractionated external beam radiotherapy.

Proposed Patient Pathway

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

The alternative treatment option is either surgery or fractionated radiotherapy.

Proposed Governance Arrangements

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

Some of the RT doses used in the literature review are comparatively uncommon in clinical usage e.g. 14Gy or above in single fraction; 18-21Gy or above in 3 fractions and COULD be associated with lower efficacy and/or a higher risk of radiation myelopathy than the more commonly used conventionally fractionated treatment eg 50 Gy in 25-28 fractions.

In the neurosciences MDT,it is important to discuss available evidence on efficacy and morbidity of these respective RT approaches(Kirkpatrick JP et al Radiation dose-volume effects in the spinal cord Int J Radiat Oncol Biol Phys 2010 Mar 1;76(3 suppl) S42-9.

Some schwannomas may be associated with NF2 syndrome; discussion should take place as to whether it is best to avoid RT altogether in terms of its known propensity to form second tumours in this situation

Proposed Mechanism for Funding

There is no national tariff for SABR and is locally agreed by Regional Specialised Commissioning Teams

Proposed Audit Requirements

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

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.p df. 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.

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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