NHS England

Clinical Commissioning Policy Proposition:

The use of Stereotactic Ablative Radiotherapy (SABR) as a treatment option for patients with Renal Cancer

Reference: NHS England B01X29

Clinical Commissioning Policy Proposition: The use of Stereotactic Ablative Radiotherapy (SABR) as a treatment option in the management of patients with renal cancer.

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1 Executive Summary

Policy Statement

NHS England proposes to not routinely commission Stereotactic Ablative Radiotherapy in the treatment of patients with renal cancer.

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 renal cancer.

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 patients with renal cancer.
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 an option in the treatment of patients with renal cancer 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 to treat renal cancer.

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.

Renal Cancer

Renal cell carcinoma is a malignancy that originates in the lining of the proximal convoluted tubule of the kidney. The condition, usually described as renal carcinoma or renal cancer, is the most frequent malignant disorder of the kidney in adults, but is uncommon, accounting for only about 3% of cancers in the United Kingdom; its annual incidence is about 13 per 100,000. The incidence is apparently rising, but this probably reflects the incidental detection of radiological abnormalities in the kidney when patients are scanned for other reasons. This has led to annual increases in the detection of renal cancers of about three percent, with the incidence of small renal tumours increasing at a faster rate. Lesions detected in this way may have a more favourable prognosis than those which present with symptoms.

Initial treatment is most commonly a radical or partial nephrectomy. Where the tumour is confined to the renal parenchyma, the five-year survival rate is 60% to 70%, but it is much lower when metastasis has occurred. Small tumours may be treated non-invasively with cryotherapy and radio-frequency ablation, both of which are the subject of guidance from the National Institute for Health and Care Excellence.[1][2][3] Renal cancer is relatively resistant to radiation therapy and chemotherapy, but sunitinib, temsirolimus, bevacizumab and other forms of immunotherapy can have some effect.

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 to treat patients with renal cancer.
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 studies were identified in the review commissioned for the development of this policy which were restricted to people with inoperable renal cancer. The search was therefore widened to include all studies of SABR for renal cancer. No randomised controlled trials were identified.

One systematic review of SABR for renal cancer Siva et al (2012) was identified:

- The authors, Siva et al, found ten papers reporting a total of 126 participants; three studies were prospective and seven retrospective. None of the studies were controlled. Technique and dose fractionation "varied widely", with three-, four- and five-fraction regimes most commonly reported. The most common total dose was 40 Gy. Little further information is available, for example on the median ages of the participants or the use of other treatments. There is no information on whether the tumours were biopsied before treatment – this is not always the case with renal tumours, and some tumours are treated as malignant despite being histologically benign.

- After follow-up ranging from nine to fifty-eight months, local control rates varied from 84% to 100%. Without testing for heterogeneity, Siva et al crudely weighted the control rates according to the studies' sizes, and calculated average rates of 93.1% for overall local control and 92.9% for local control at two years. A more sophisticated approach would have been to include studies' duration in the weighting, though the heterogeneity of the studies casts doubt on the appropriateness of pooling the results at all.

- Siva et al note the inconsistent reporting of survival after treatment. Six of the ten studies did not report survival at all, while the results from the remaining four varied widely. They reported respectively median survival of "58+"

months, a five-year survival rate of 74%, median survival of 32 months and that four of nine participants were still alive when the study closed.

No published studies since Siva et al's search date (2012) were identified, nor any published before that date which the authors did not include.

7. Evidence Base

The evidence regarding the effectiveness and safety of SBRT / SABR for treating patients with renal cancer 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.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.

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).

References

Renal cancer

National Institute for Health and Clinical Excellence. Percutaneous cryotherapy for renal cancer. London: NICE, 2011. (IPG 402).

National Institute for Health and Clinical Excellence. Laparoscopic cryotherapy for renal cancer. London: NICE, 2011. (IPG 405).

National Institute for Health and Clinical Excellence. Percutaneous radiofrequency ablation for renal cancer. London: NICE, 2010. (IPG 353).

Siva S, Pham D, Gill S, et al. A systematic review of stereotactic radiotherapy ablation for primary renal cell carcinoma. BJU Int 2012; 110: E737-43.