NHS England

Clinical Commissioning Policy: The use of Stereotactic Ablative Radiotherapy (SABR) in the treatment of Prostate Cancer

Reference: NHS England: 16031/P

NHS England INFORMATION READER BOX		
Directorate		
Medical	Operations and Information	**Specialised Commissioning**
Nursing	Trans. & Corp. Ops.	Commissioning Strategy
Finance		

Publications Gateway Reference:	**05527s**
Document Purpose	Policy
Document Name	Clinical Commissioning Policy 16031/P
Author	Specialised Commissioning Team
Publication Date	13 July 2016
Target Audience	CCG Clinical Leaders, Care Trust CEs, Foundation Trust CEs , Medical Directors, Directors of PH, Directors of Nursing, NHS England Regional Directors, NHS England Directors of Commissioning Operations, Directors of Finance, NHS Trust CEs
Additional Circulation List	
Description	Not Routinely Commissioned - NHS England will not routinely commission this specialised treatment in accordance with the criteria described in this policy.
Cross Reference	This document is part of a suite of policies with Gateway Reference 05527s.
Superseded Docs (if applicable)	N/A
Action Required	N/A
Timing / Deadlines (if applicable)	**N/A**
Contact Details for further information	england.specialisedcommissioning@nhs.net

Document Status

This is a controlled document. Whilst this document may be printed, the electronic version posted on the intranet is the controlled copy. Any printed copies of this document are not controlled. As a controlled document, this document should not be saved onto local or network drives but should always be accessed from the intranet.

Clinical Commissioning Policy: The use of Stereotactic Ablative Radiotherapy (SABR) in the treatment of Prostate Cancer

First published: July 2016

Prepared by NHS England Specialised Services Clinical Reference Group for Radiotherapy

Published by NHS England, in electronic format only.

Contents

Policy Statement

NHS England will not routinely commission the use of stereotactic ablative radiotherapy for prostate cancer 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 prostate cancer.

About SABR treatment

Stereotactic body radiotherapy (SABR) is a highly targeted radiation therapy which targets a tumour with radiation beams from different angles at the same time:

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

SABR is delivered in between 1 and 8 treatments (called ‘fractions’).

What we have decided

NHS England has carefully reviewed the evidence to treat prostate cancer with Stereotactic body radiotherapy. 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 prostate cancer. 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 prostate cancer.

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. 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.

3 Aims and Objectives

This policy considered whether there is sufficient robust evidence of clinical and cost-effectiveness and safety to support the use of SABR in the treatment of patients with prostate cancer.

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

Prostate cancer is the commonest cancer among British males. It affects about one in twelve men over a lifetime, giving rise each year to about 30,000 new cases and 10,000 deaths. Prostate cancer is particularly common among older men; two-thirds of those who die from prostate cancer are over the age of 75 years. Prostate cancer may be diagnosed when men are investigated for benign prostate disease, also a common condition in elderly men.

The disease varies widely in its clinical course, tending to be more aggressive in younger men. Sometimes prostate cancers grow so slowly that they pose no threat to health or longevity – autopsies in men over eighty years of age show that most have malignant tissue in their prostate glands, but they died with prostate cancer, not of it. Survival rates are better than for many other cancers.

External beam radiotherapy is widely used to treat prostate cancer. Compared with external beam radiotherapy, SABR offers the potential advantages of delivering a higher dose to the tumour with less collateral damage to normal tissue, and of requiring fewer fractions.

5 Evidence Base

The evidence regarding the effectiveness and safety of SABR for treating patients with prostate cancer has been used as a basis for this commissioning policy. The

evidence base indicates that there is insufficient evidence to routinely commission SABR for this cohort of patients.

For prostate cancer, a systematic review Tan et al (2014), was identified:

- The authors found no controlled trials of the effectiveness of SABR for prostate cancer. 14 uncontrolled studies which reported a total of 1472 participants were identified and included. Biochemical progression-free survival was more than 81% in all the studies, after median follow-up of 11 to 60 months.
- The systematic review reported that the commonest form of acute toxicity was urinary, with grade 1 (least severe) adverse effects reported in 20% to 74% of participants. Grade 1 acute rectal toxicity occurred in 3% to 75% of participants.
- The review included four studies reporting quality of life, three uncontrolled and one controlled. Of the three which were uncontrolled, two reported that quality of life declined in the first few months after SABR but then returned to baseline levels (King et al 2013, Friedland et al 2009), and one reported no overall changes (Chen et al 2012).
- The fourth study (Katz et al 2012) compared radical prostatectomy with SABR. It reported that the men who had SABR had smaller and briefer declines in quality of life related to urinary symptoms, and avoided the loss of sexual quality of life that followed prostatectomy. There was a larger and more prolonged decline in bowel quality of life after SABR than after surgery. This study is unreliable because of marked confounding between the two groups.
- A controlled study (Katz et al 2014) reporting oncological outcomes published since the search date of the systematic review, was also identified. It compared SABR with or without external beam radiotherapy in men with high-risk non-metastatic prostate carcinoma, and reported that five-year biochemical disease-free survival was 68% overall, which was similar in the two groups. This study may suggest that SABR alone is as effective SABR plus external beam radiotherapy, but needs to be interpreted with caution due

to methodological caveats including the non-randomisation of the study, and lack of power calculation to determine clinically significant result threshold.

- A controlled study Yu et al (2014) reported that SABR was associated with more genito-urinary and gastro intestinal adverse events than IMRT

Three studies relating to cost effectiveness of SABR for prostate cancer were identified:

- Hodges et al (2012) used Markov modelling to estimate the cost effectiveness of SABR and IMRT for organ-confined prostate cancer in a man of 70 years. The authors assumed the two treatments were equally efficacious in terms of progression-free survival, and produced equal quality of life; the latter assumption is not compatible with the subsequent findings of Yu et al (2014). Costs were based on the US health care system in 2010. IMRT cost $29,530 (£19.400) and SABR $14,315 (£9400).

- It followed from these assumptions that the lower cost of IMRT yielded a lower cost per quality-adjusted life-year (QALY) (IMRT $35,431 (£23,300) versus $22,152 (£14,600) for SABR). Hodges et al varied their assumptions using sensitivity analysis, but SABR had an incremental cost effectiveness ratio of less than $50,000 in 66% of iterations.

- Sher et al's (2014) approach was similar to that of Hodges et al (2012). They derived their estimates of treatment efficacy and toxicity from published sources; it is not clear how they reconciled disparate results. Costs were from the 2012 Medicare tariff. The base case analysis indicated that IMRT yielded slightly more QALYs than SABR, but was also more expensive, with costs per QALY of $3,400 (£2200), compared with $2600 (£1700) for robotic SABR and $1700 (£1100) for non-robotic SABR. Sensitivity analysis indicated that SABR was cost-effective under most sets of parameter assumptions.

- Parthan et al (2012) also published a similar analysis, which also included proton beam therapy. They based their assumptions about treatment efficacy

on uncontrolled studies, which they meta-analysed without assessing heterogeneity. Costs were based on the US Medicare tariff.

- Like Hodges et al (2012), Parthan et al (2012) concluded that SABR was the most cost effective treatment, with a cost per QALY of $3100 (£2000). IMRT and proton beam therapy had incremental costs per QALY versus SABR of $8195 (£5400) and $46,560 (£30,600). Sensitivity analysis made little difference, with SABR more cost-effective than IMRT and proton beam therapy in 75% and 94% of simulations respectively.

These studies relating to cost-effectiveness reach similar conclusions: that the lower costs of SABR (related to the lower number of fractions) lead to it to have better apparent cost effectiveness that IMRT. However it should be noted that:

- All studies were based on US healthcare costs, which differ from those in the NHS
- It is unclear how extra capital costs of SABR equipment has been modeled in these studies
- Data on efficacy and toxicity are derived from uncontrolled non-randomised studies
- Analyses only compare SABR with other forms of radiotherapy, and do not account for efficacy of other treatments for example hormone treatment and active monitoring.

6 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.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 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

Arscott WT, Chen LN, Wilson N, et al. Obstructive voiding symptoms following stereotactic body radiation therapy for prostate cancer. Radiat Oncol 2014; 9: 163-72.

Bhattasali O, Chen LN, Woo J, et al. Patient-reported outcomes following stereotactic body radiation therapy for clinically localized prostate cancer. Radiat Oncol 2014; 9: 52-62.

Chen LN, Suy S, Uhm S, et al. Stereotactic body radiation therapy (SBRT) for clinically localized prostate cancer: the Georgetown University experience. Radiat Oncol 2013; 8: 58.

Friedland JL, Freeman DE, Masterson-McGary ME, Spellberg DM. Stereotactic body radiotherapy: an emerging treatment approach for localized prostate cancer. Technol Cancer Res Treat 2009; 8: 387-92.

Hodges JC, Lotan Y, Boike TP, et al. Cost-effectiveness analysis of SBRT versus IMRT: an emerging initial radiation treatment option for organ-confined prostate cancer. Am J Manag Care 2012; 18: e186-93.

Katz A, Ferrer M, Suárez JF, et al. Comparison of quality of life after stereotactic body radiotherapy and surgery for early-stage prostate cancer. Rad Oncol 2012; 7: 194-203.

Katz AJ, Kang J. Stereotactic body radiotherapy as treatment for organ confined low- and intermediate-risk prostate carcinoma, a 7-year study. Front Oncol 2014; 4: 240.

Katz A, Kang J. Stereotactic body radiotherapy with or without external beam radiation as treatment for organ confined high-risk prostate carcinoma: a six year study. Radiat Oncol 2014; 9: 1.

King CR, Collins S, Fuller D, et al. Health-related quality of life after stereotactic body radiation therapy for localized prostate cancer: results from a multi-institutional consortium of prospective trials. Int J Radiat Oncol Biol Phys 2013; 87: 939-45.
Parthan A, Pruttivarasin N, Davies D, et al. Comparative cost-effectiveness of stereotactic body radiation therapy versus intensity-modulated and proton radiation therapy for localized prostate cancer. Front Oncol 2012; 2: 81.

Sher DJ, Parikh RB, Mays-Jackson S, Punglia RS. Cost-effectiveness analysis of SBRT versus IMRT for low-risk prostate cancer. Am J Clin Oncol 2014; 37: 215-21.

Tan TJ, Siva S, Foroudi F, Gill S. Stereotactic body radiotherapy for primary prostate cancer: a systematic review. J Med Imaging Radiat Oncol 2014; 58: 601-11.

Yu JB, Cramer LD, Herrin J, et al. Stereotactic body radiation therapy versus intensity-modulated radiation therapy for prostate cancer: comparison of toxicity. J Clin Oncol 2014; 32: 1195-201.