

Clinical Commissioning Policy Statement

Proton Beam Therapy for Head and Neck Cancer in Adults

(URN: 1873) [190703P]

Publication date: July 2019 **Version number:** 1.0

Commissioning Position

Summary

NHS England has reviewed the evidence to treat head and neck cancer in adults with proton beam therapy and have concluded that there is not enough evidence to make the treatment available through routine commissioning. This excludes any routinely commissioned indications referred to in the NHS England 'Clinical Commissioning Policy: Proton Beam Radiotherapy (High Energy) for Skull Base Tumour Treatment' (2015).

Information about proton beam therapy in head and neck cancer

The intervention

Proton Beam Therapy (PBT) provides radiation by delivering a beam of proton particles rather than X-Rays. The physical properties of protons can result in a significantly reduced dose being deposited in the normal tissue beyond the tumour. This is in contrast to X-Rays where there is low dose extension beyond the tumour. This can have some advantages over conventional radiotherapy in certain groups of patients, such as children, or where the cancer is close to a critical part of the body such as the spinal cord.

Radiotherapy is routinely offered as a curative treatment for head and neck cancer. However, this can result in significant side effects. PBT may have the potential to cause less damage to surrounding tissues, and therefore cause less acute and late radiotherapy side effects, while maintaining cure rates. However, the current evidence is insufficient to support the routine commissioning of PBT for head and neck cancer.

Committee discussion

The condition

Head and neck cancers comprise of a variety of diagnoses. These include cancers of the nasopharynx, oropharynx, larynx, hypopharynx and salivary glands. In 2016, there were 9347 cases of head and neck cancer registered in England, accounting for approximately 3% of all cancers (Cancer Research UK, 2018). Head and neck cancers are usually squamous cell carcinoma. Many head and neck cancers are curable, and cure rates depend on location and spread of disease.

Current treatments

Head and neck cancer often requires a multidisciplinary approach including combinations of surgery, radiotherapy and chemotherapy. Most patients require either upfront or post-operative radiotherapy. The use of intensity-modulated radiotherapy (IMRT) is the international and UK standard. Many localised head and neck cancers are curable, but this can be at the expense of significant side effects.

Acute side effects from head and neck IMRT are common and include fatigue, mouth and throat pain, mouth dryness, taste disturbance, reduced oral intake and difficulty with swallowing. Difficulty in swallowing can result in pneumonia, requirement for tube feeding and hospital

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admissions. Late side effects include mouth dryness, taste disturbance, difficulty with swallowing, hearing and visual loss, hormone dysfunction, jaw stiffness and bone damage. These can impact on long-term quality of life for patients (Wang & Eisbruch, 2016).

Comparators

Curative treatment options for head and neck cancer are radiotherapy alone or combined with chemotherapy, or surgery. Following surgery, patients may require a course of radiotherapy with or without chemotherapy.

Clinical trial evidence

Three papers were requested by the Clinical Panel as part of the policy proposition. One contained the findings from a patient reported outcomes survey. The other two papers were review articles (which reflects the broad nature of this 'not for routine commissioning policy' for adult head and neck cancers). These summarise the current low level of evidence in the literature regarding the use of proton beam therapy for the routine treatment of adult head and neck cancers. They did not provide data from primary research and did not add to the evidence on the clinical or cost effectiveness of proton beam therapy.

The Panel found insufficient evidence to demonstrate the superiority of proton beam therapy over current standard treatment (IMRT) to justify routine commissioning for this indication.

Paper 1: Sio et al. 2016

Intensity Modulated Proton Therapy versus Intensity Modulated Photon Radiation Therapy (IMRT) for Oropharyngeal Cancer: First Comparative Results of Patient-Reported Outcomes.

Sio et al report findings of a study that retrospectively reviewed the patient reported outcomes of a group of 81 patients with oropharyngeal cancer who were treated either with proton beam therapy or IMRT. 35 of the patients had been treated with chemotherapy and proton beam therapy and 46 had been treated with chemotherapy and IMRT. The survey information was collected prospectively during the course of treatment but the comparing of the outcomes in the two groups reported here was done retrospectively.

No differences in symptom burden were detected between treatment modalities during the acute and chronic phases when the patients' responses were analysed by the top 11 most severe symptoms – taste disturbance, dry mouth, swallowing and chewing, fatigue, pain, appetite, mucus, sleep, mouth sores, drowsiness and distress. A difference was recorded amongst the patients in the subacute recovery phase with the proton beam therapy patients recording a lower symptom burden.

The study has several limitations. The retrospective analysis of the data could have skewed the findings as the parameters for this analysis were determined after the data were collected. There was also a significant difference in the timing of the treatment for the two groups so any difference in symptoms, could have been the result of other cancer care protocols other than the two therapies under comparison. The absence of data from the post treatment phase is another shortcoming as that phase is particularly relevant in the articulation of the long-term benefit of proton over photon therapy. There were imbalances between the two groups including the proportion of patients receiving induction chemotherapy. The setting of the survey is an insurance based payment system, which may be a confounding factor.

In conclusion, the authors suggest the need for prospective trials with patient reported outcomes to define the value of proton beam therapy in the management of oropharyngeal tumours.

Paper 2: Leeman et al 2017

Proton Therapy for head and neck cancer: Expanding the therapeutic window

This is a review of the potential use of proton beam therapy in the treatment of a wide range of head and neck cancers. There is no primary research data in the paper. The authors highlight the significant challenges of using photon based radiation for head and neck cancers. In addition to summarising previous studies that have evaluated the toxicity of proton beam therapy versus photon radiotherapy, the authors consider the use of proton beam therapy in unilateral head and neck irradiation, oropharyngeal cancer, nasopharyngeal cancer, sinonasal cancer and tumours of the skull base. The authors conclude that at present the use of proton beam therapy for most head and neck cancers should be in the context of a clinical trial.

Paper 3: Blanchard et al 2018

Proton Therapy for Head and Neck Cancers

The paper does not contain the findings from primary research but is a review paper that summarises the clinical benefit for the use of proton beam therapy for various disease sites. The main assertion of the authors is that proton beam therapy has a wider role than the generally accepted use in skull-base tumours. For other sites they highlight the physical properties and dosimetric benefit of proton beam therapy over advanced photon radiotherapy include the nasopharynx, oropharynx, nasal cavity paranasal sinuses, periorbital tumours, skin and salivary glands. The authors conclude that proton beam therapy is a technical development of radiation therapy and prospective trials would help to further evaluate its clinical efficacy as well as to quantify the toxicity.

The current available evidence does not demonstrate that proton beam therapy offers a superior clinical benefit in the management of a wide range of head and neck cancers.

Adverse events

Adverse events were not demonstrated in the literature provided.

Policy review date

This is a policy statement, which means that the full process of policy production has been abridged: a full independent evidence review has not been conducted; and public consultation has not been undertaken. If a review is needed due to a new evidence base then a new Preliminary Policy Proposal needs to be submitted by contacting the specialised commissioning Clinical Effectiveness Team email.

Links to other Policies

Radiotherapy Service Specification (<https://www.england.nhs.uk/wp-content/uploads/2013/06/b01-radiotherapy.pdf>)

Clinical Commissioning Policy: Proton Beam Radiotherapy (High Energy) for Skull Base Tumour Treatment' (2015). <https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2015/10/b01-pd-prtn-bm-thrpy-adlts-oct15.pdf>

Documents that have informed this policy statement

Blanchard P., Gunn G.B., Lin A., Foote R.L., Lee N.Y & Frank S.J. Proton Therapy for Head and Neck Cancers. *Semin Radiat Onco.* 2018 Jan;28(1):53-63.

Leeman J.E., Romesser P.B., Zhou Y., McBride S., Riaz N, Sherman E. et al. Proton therapy for head and neck cancer: expanding the therapeutic window. *Lancet Oncol.* 2017 May;18(5):e254-e265.

Sio T.T., Lin H.K., Shi Q., Gunn G.B., Cleeland C.S., Lee J.J. et al. Intensity Modulated Proton Therapy Versus Intensity Modulated Photon Radiation Therapy for Oropharyngeal Cancer: First Comparative Results of Patient-Reported Outcomes. *Int J Radiat Oncol Biol Phys.* 2016 Jul 15;95(4):1107-14.

Additional References

Cancer Research UK website, <https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/head-and-neck-cancers> ; accessed December 2018.

Wang X. & Eisbruch A. IMRT for head and neck cancer: reducing xerostomia and dysphagia. *J Radiat Res.* 2016 Aug; 57(Suppl 1):i68-i75.