



Effective Health Care Charged-Particle Radiation Therapy for Cancer Nomination Summary Document

Results of Topic Selection Process & Next Steps

- Charged-particle radiation therapy for cancer was found to be addressed by two AHRQ products. Given that the existing work covers this nomination, no further activity will be undertaken on this topic.
 - Trikalinos TA, Terasawa T, Ip S, Raman G, Lau J. Particle Beam Radiation Therapies for Cancer. Technical Brief No. 1. (Prepared by Tufts Medical Center Evidence-based Practice Center under Contract No. HHSA-290-07-10055.) Rockville, MD: Agency for Healthcare Research and Quality. Revised November 2009. Available at: www.effectivehealthcare.ahrq.gov/reports/final.cfm.
 - Terasawa T, Dvorak T, Ip S, Raman G, Lau J, Trikalinos TA. Systematic review: charged-particle radiation therapy for cancer. *Ann Intern Med.* 2009 Oct 20;151(8):556-65. PMID: 19755348
- Charged-particle radiation therapy for cancer could potentially be considered for new research in comparative effectiveness.

Topic Description

Nominator: Individual

Nomination Summary: The nominator questions whether heavy charged particle therapy (e.g., using carbon ions, helium ions) was more cost-effective than conventional (photon) or proton beam radiotherapy (RT) for treatment of sarcomas, chondromas, melanomas, base of skull tumors, and lung cancer in persons with locally extensive tumor that tends to be resistant to conventional radiotherapy and is not readily accessible

Staff-Generated PICO: Comparative effectiveness of charged particle radiation therapy and conformal radiotherapy

Population(s): Adult and pediatric patients with cancer (inoperable sarcomas, chondromas, melanomas (uveal), lung cancer (NSCLC), or head and neck cancers), stratified by risk where feasible

Intervention(s): CPRT with protons, carbon or helium ions (among others), excluding neutron or π -meson particles.

Comparator(s): Conformal radiation therapy with photons/X-rays (e.g., 3D-CRT, IMRT, IORT, SBRT, IGRT, brachytherapy)

Outcome(s): Overall survival; disease-specific survival; local control; adverse effects of radiation; health-related quality of life

Staff-Generated PICO: Comparative effectiveness of charged particle radiation therapy and other forms of radiation therapy

Population(s): Adult and pediatric patients with cancer (inoperable sarcomas,

chondromas, melanomas (uveal), lung cancer (NSCLC), or head and neck cancers), stratified by risk where feasible

Intervention(s): CPRT consisting of carbon or helium ions (among others), excluding protons, neutron or π -meson particles

Comparator(s): Proton-beam radiation therapy; conformal RT with photons/X-rays (e.g., 3D-CRT, IMRT, IOMT, SBRT, IGRT, brachytherapy)

Outcome(s): Overall survival; disease-specific survival; local control, adverse effects of radiation; health-related quality of life

Key Questions from Nominator:

1. Is heavy charged particle therapy likely to be more cost-effective than conventional or proton beam radiotherapy for treating cancer?

Considerations

- The topic meets Effective Health Care (EHC) Program appropriateness and importance criteria. (For more information, see <http://effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/how-are-research-topics-chosen/>.)
- Topic was found to be addressed by a 2009 AHRQ Technical Brief titled *Particle Beam Radiation Therapies for Cancer* and an updated publication of this Technical Brief titled *Systematic review: charged-particle radiation therapy for cancer*. Key questions from the 2009 Technical Brief include:

Key question 1:

- 1.a. What are the different particle beam radiation therapies that have been proposed to be used on cancer?
- 1.b. What are the theoretical advantages and disadvantages of these therapies compared to other radiation therapies that are currently used for cancer treatment?
- 1.c. What are the potential safety issues and harms of the use of particle beam radiation therapy?

Key question 2:

- 2.a. What instrumentation is needed for particle beam radiation and what is the Food and Drug Administration (FDA) status of this instrumentation?
- 2.b. What is an estimate of the number of hospitals that currently have the instrumentation or are planning to build instrumentation for these therapies in the US?
- 2.c. What instrumentation technologies are in development?

Key question 3:

Perform a systematic literature scan on studies on the use and safety of these therapies in cancer, with a synthesis of the following variables:

- 3.a. Type of cancer and patient eligibility criteria
- 3.b. Type of radiation, instrumentation and algorithms used
- 3.c. Study design and size
- 3.d. Comparator used in comparative studies.
- 3.e. Length of followup
- 3.f. Concurrent or prior treatments
- 3.g. Outcomes measured
- 3.h. Adverse events, harms and safety issues reported

Importance of New Research

- Controversy exists regarding the clinical use of CPRT due to the uncertainty in the evidence and guidance. Limited clinical guidance exists for CPRT, and only for proton therapy. In general, proton therapy is not recommended for routine use due to limited evidence of effectiveness and lack of consensus among experts.

Research Gaps

- The AHRQ 2009 Technical Brief included a discussion of gaps in proton therapy research that need to be addressed, including:
 - Prioritization of the cancers, particularly for more common cancers, for which there is genuine uncertainty surrounding the theoretical advantages of charged particle therapy and their contemporary alternatives.
 - Comparative studies and RCTs (when feasible), along with concomitant economic evaluations, to document the comparative efficacy, safety, and costs of charged particle therapy relative to contemporary interventions for specific clinical situations.
 - Prospective comparative studies to study the theorized reductions in the rate and severity of harms with particle beam therapy compared with conventional therapies.
 - Further study of the technical and clinical delivery methodologies to optimize charged particle radiotherapy protocols.