

Carbon Ion Radiation Therapy

- PAR 13-371: Planning for a National Center for Particle Beam Radiation Therapy Research (P20).
 - Applications in review process at present.
- SPL suggested funding randomized clinical trials of CIRT at facilities in Europe and Asia.

Carbon Ion Radiation Therapy

- CIRT has been administered, mostly in Japan, to several thousand cancer patients.
- In single-arm trials it is reported to be substantially more effective than photons or protons against some “radioresistant” cancers such as Pancreatic ca, HCC, Rare sarcomas, Rare H&N ca, Recurrent rectal ca.
- No RCT have been performed in Japan or are proposed.

Biological dose vs Physical Dose for Heavy Ions

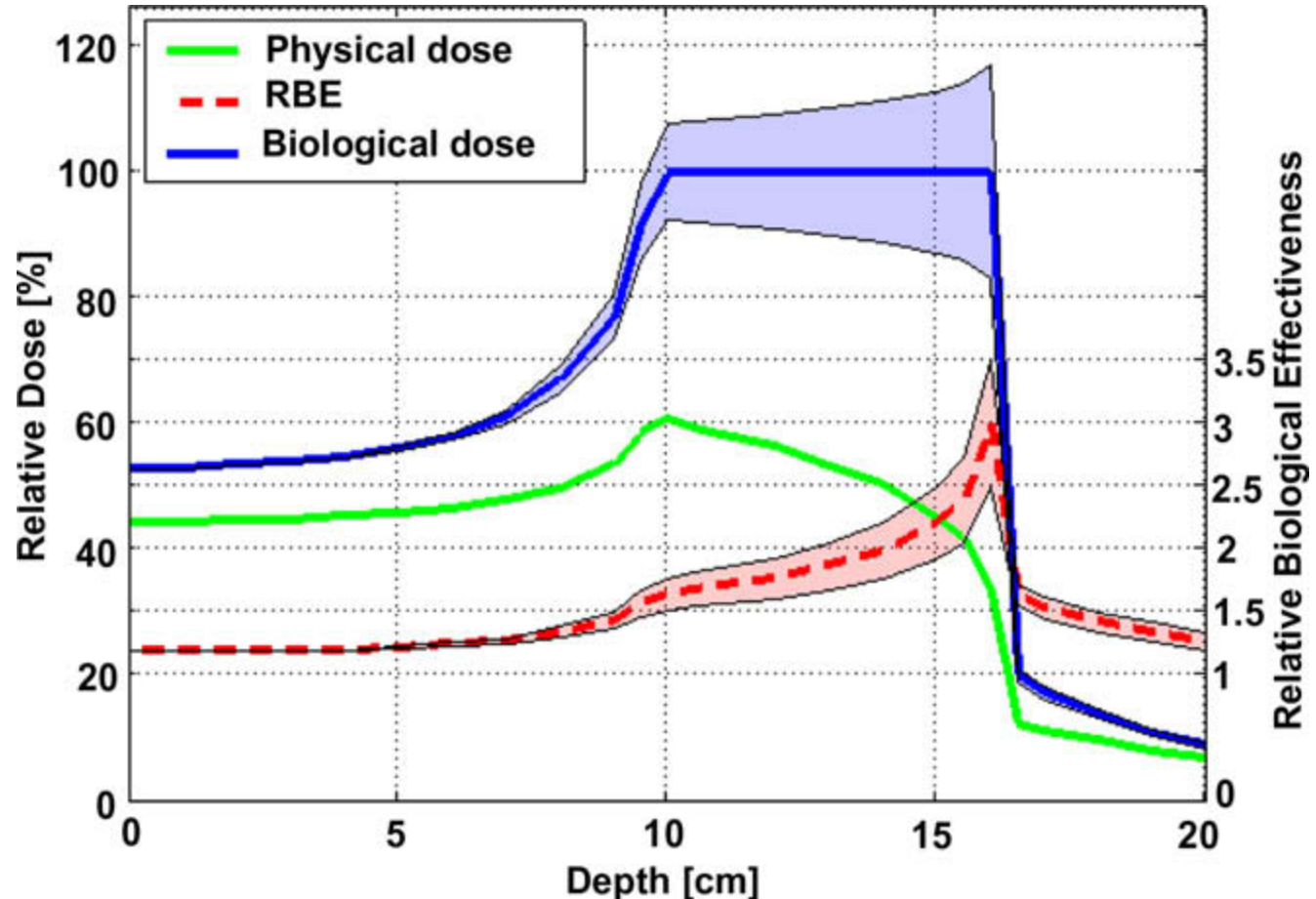
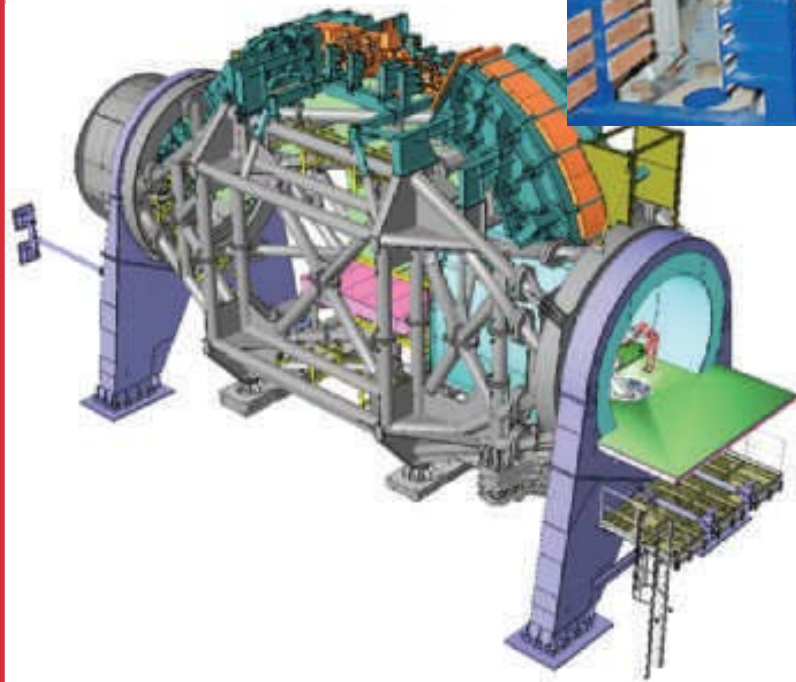


Fig. 8. Design of a 290 MeV ^{12}C ion beam with a 6 cm SOBP for an assumed maximum RBE of 3.0. The impact of an error in selecting the RBE were the true RBE in the range of 2.5–3.5 is represented by the uncertainty bands around the dose in Gy(RBE) across the SOBP. (H. Suit et al. / Radiotherapy and Oncology 95 (2010) 3–22)

Expensive with Long Lead Times



Proton RT-History

- Based upon similar uncontrolled trials protons were claimed superior to photons.
- The first hospital-based proton facility opened in the US over 20 years ago.
- No RCT were started until very recently, while the number of facilities has mushroomed, accompanied by heavy marketing.

Rationale

- Proton facilities cost ~\$150 million.
- CIRT facilities cost ~\$300 million.
- Before CIRT facilities begin cropping up in the US it seems prudent to sponsor some RCT abroad for determining their value.

Proposal

- Under a contract conduct a RCT in locally advanced, unresectable Pancreatic Ca comparing CIRT versus Standard RT.
- The 2-year OS after Standard RT is ~10%. Recent Japanese data suggest 54%!
- NRG Oncology is comparing Standard RT vs Dose Intensified IMRT, aiming to increase 2 year OS from 10% to 22.5% (RTOG 1201).
- Identical Eligibility criteria, Control arm and Systemic therapy are planned.

Budget

- Up to \$2M total.
- Total duration 5 years (6 mos start up, 3 years accrual, 1 year follow up).
- Analysis in coordination with RTOG 1201.
- Questions: Storage and sharing of Data, Images, Biospecimens, etc?