ASTRO ETC Proton Therapy Report

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Disclosures

- Financial –None
- The views that I will be going to express in this talk are not the views of ASTRO

History

- ETC started by Dr. Ted Lawrence
- Original Co-Chairs Drs. Paul Wallner and Andre Konski
- Started Oct 2005
- Proton Therapy report initiated May 2007
- All sections completed 1/09 and sent to Evaluation Subcommittee Chairs
- Report to be also sent to ASTRO Proton Therapy Task Force

History

- July 28 2009- Final report ready for final review
- Sent to select group of reviewers from ESTRO
  - Philip Lambin, Michael Bauman, Dag Rune Olsen, Jens Overgaard and Michael Joiner (USA Biology review)
  - Expert review completed 9/2009
- Final report 11/09
- Sent to Proton Task Force 12/09
- Proton Task Force completed 3/10

History

- ASTRO legal review completed 4/10
- Public comments on the report received 6/10
- Original report was 100+ pages with over 200 references
- Proton report submitted to Cancer-Rejected
- Proton report submitted to JNCI-Rejected
- Proton report submitted to JCO-Rejected
- Proton report submitted to PRO-Rejected

History

- Submitted to Radiotherapy & Oncology Oct/11
- Rejected, Resubmitted and Received in revised form 1/12
- Accepted 2/12
- Available on line 3/12
- For all of you Oliver Stone fans
  - Why is an official work product of ASTRO published in the official journal of ESTRO?

- Full report available on line at:
  - https://www.astro.org/uploadedFiles/Content/Clinical_Practice/ProtonBeamReport.pdf

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Systematic review

An evidence based review of proton beam therapy: The report of ASTRO's emerging technology committee

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Topics

- CNS
- Lung
- Ocular Melanoma
- GI
- Prostate
- Head and Neck
- Pediatrics

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CNS

- Clinical data from PBT or mixed photon/PBT for base of skull tumors appear superior to previously published series of conformal photon radiotherapy
- However, stereotactic photon radiosurgery may provide a significant dosimetric and clinical advantage to standard conformal (3D or IMRT) radiotherapy techniques.
- Overall, more clinical data (published clinical trials) are needed to fully establish the role of PBT in CNS tumors.

Lung

- PBT has been used in the treatment of stage I NSCLC although no clear clinical benefit over photon therapy has currently been shown.
- Data regarding the use of PBT in other clinical scenarios remain limited and do not provide sufficient evidence to recommend PBT for lung cancer outside of clinical trials.
- In addition, unlike in some other disease sites, the issue of organ motion in lung cancer is critical and adds an additional challenge to the use of PBT.

GI

- PBT is mostly untested in GI malignancies, and the number of patients with GI malignancies who are eligible for PBT will be very small until indications for its use become clearer.
- In rectal and gastric cancers there appears to be little role for PBT.

GI

- In esophageal and pancreatic cancers there may be a rationale for PBT, as these are two sites often with localized unresectable disease near critical organs at risk, but almost no clinical data exist.
- In hepatocellular cancer there appears to be the most data and perhaps promise for PBT as an alternative to photon base approaches, but more rigorous study and prospective clinical trials are necessary to definethe differences in toxicity and efficacy between protons and photons.

Ocular Melanoma

- PBT has been shown to be effective in the treatment of large ocular melanomas not approachable via brachytherapy.
- In the group of intermediate tumors that has been well studied by the COMS (Collaborative Ocular Melanoma Study) group, there is evidence for efficacy of both PBT and brachytherapy.
- Further comparative studies will help select patients for the appropriate therapy.

Prostate

- Most patients treated with protons
- No clear evidence from both in terms of outcome and toxicity
- Head to head clinical trials needed
  - Actually going to happen at Penn and MGH
- Based on current data, proton therapy is an option for prostate cancer, but no clear benefit over the existing therapy of IMRT photons has been demonstrated.

Head and Neck Cancer

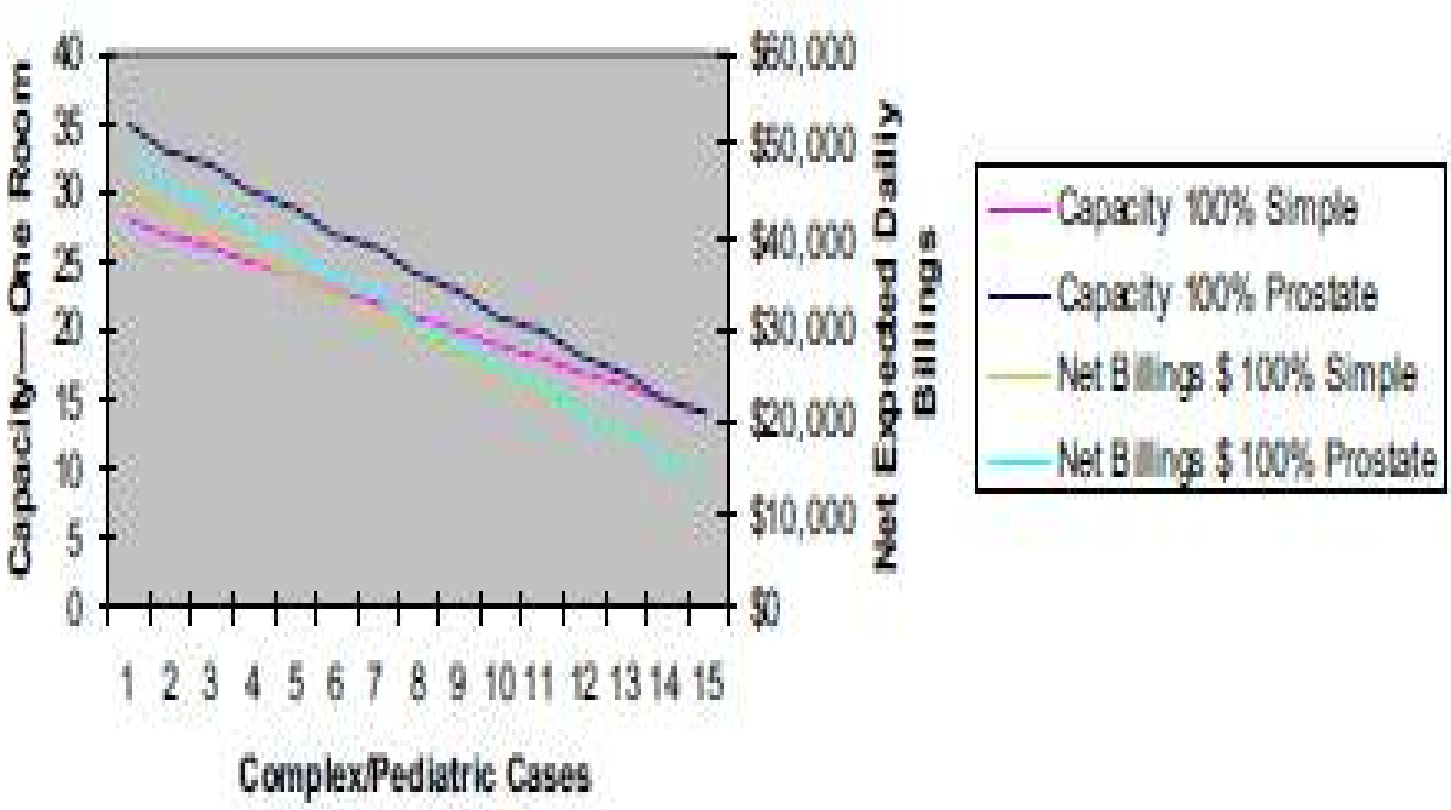
- Until IMPBT is more fully developed and tested, it will be difficult to establish whether PBT may be equivalent to photon IMRT in treating full head and neck plans.
- Further clinical data through prospective clinical trials are needed regarding cases in which the target is the primary volume located near critical structures.
- There are insufficient data to recommend PBT for routine head and neck radiation therapy outside of clinical trials.

Pediatrics

- PBT has perhaps its most developed place in pediatric brain tumors.
- Although the clinical evidence is lacking, the rationale for using PBT in posterior fossa tumors, optic pathway tumors, and brainstem lesions is compelling.
- Future clinical studies reporting on the outcome of patients treated with protons will decide how widespread protons become for pediatric CNS tumors.

Pediatrics

- There does not appear to be sufficient evidence at this time to recommend treatment with protons for non-CNS pediatric malignancies.



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California Technology Assessment Forum (CTAF)

- Blue Shield Foundation of California spearheads the California Technology Assessment Forum (CTAF), managing technology assessment reviews and organizing all CTAF meetings and events.
- Neither CTAF nor BSFC are revenue-generating organizations, consultant organizations, endorsers of specific technologies, advocacy organizations, or organizations that determine health plan benefit coverage.
- Recently released an assessment of Proton Beam Therapy for Prostate Cancer

CTAF Proton Assessment

- TA Criterion 1: The technology must have final approval from the appropriate government regulatory bodies.
  - Met criteria
- TA Criterion 2: The scientific evidence must permit conclusions concerning the effectiveness of the technology regarding health outcomes.
  - Met criteria

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CTAF Proton Assessment

- TA Criterion 3: The technology must improve the net health outcomes.
  - Met Criteria
- TA Criterion 4: The technology must be as beneficial as any established alternatives.
  - Criteria not met
- TA Criterion 5: The improvement must be attainable outside the investigational settings.
  - Criteria not met

CTAF Recommendation

- "It is recommended that proton beam therapy for localized prostate cancer does not
- meet CTAF criteria 4 or 5 for safety, efficacy and improvement in health outcomes."

Disease Site	Conclusion
CNS	More clinical data needed
Lung	More clinical data needed; Organ motion needs to be a addressed
Ocular Melanoma	Role for PBT
GI	Role depending upon disease sites
Prostate	Most data for this site and appears to be viable option
Head and Neck	Difficult to establish role until IMPT is established
Pediatrics	No clear evidence outside of CNS

Conclusion

- ASTRO ETC report shows there are a few sites potentially to benefit from the use of Proton Beam Therapy
- CTAF report not favorable
- Further studies as outlined needed to define role of Proton Beam Therapy