Clinical Quality Assurance for Particle Therapy
Plus ça même Plus

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Quality Assurance

- Designed to assure that the correct dose is delivered to the appropriate volume(s) in the correct patient for the appropriate indication in the optimal sequence within the multidisciplinary cancer treatment process in order to optimize the chance for cure with the lowest possible morbidity.
Quality Assurance

• QUALITY ASSURANCE IS A PROCESS
  – Integrated into much of what is done in Radiation Oncology
    • Hence QA includes a broad range of interactive activities
  – Clinical ↔ ↔ ↔ ↔ ↔ ↔ ↔ ↔ Physics
  – Real time data review for the patient under treatment
  – Long term follow-up and treatment outcome analysis
Quality Assurance

• QUALITY ASSURANCE IS A PROCESS
  – Publications from AAPM, IAEA, ICRU on photon quality assurance process/guidelines
    • Kutcher et al, AAPM Task Group # 40 : Comprehensive QA for Radiation Oncology (1994)
    • Frass et al, AAPM Task Group #53: QA for Clinical Radiotherapy Treatment Planning (1998)
  – Prescribing, recording, and reporting proton-beam therapy. ICRU Report, No. 78, (2007)
Quality Assurance

• Will try to focus in this talk on where particle process differs from that of photons
  – Will emphasize the medical/clinical aspects
  – The physician efforts, however, are very closely interdigitated with those of physics, nursing, engineering, administrators and other support staff

• Important to have an effective departmental Quality Assurance Committee
Quality Assurance Committee

• Quality Assurance Committee
  – Radiation oncologists
  – Medical physicists
  – Radiation therapists
  – Dosimetrists
  – Nursing
  – Engineering
  – Administration
Quality Assurance Committee

• Responsibility for designing an effective Quality Assurance program
  – Written policies and procedures
  – Audit methods
    • Annual selection of specific QA indicators which are identified for detailed monitoring during a particular year
  – Reporting requirements
    • Annual report
Underlying Principles

• Radiation dose response
  – Higher dose to tumor translates into higher tumor control rate
    • Steep dose gradients offer both opportunity (i.e. normal tissue sparing) and risk (marginal miss)
  – Normal tissue complication probability is related to dose and volume
Clinical Trials

- Provide the most structured set of clinical treatment guidelines
  - Written by expert(s)
  - Peer reviewed
    - Scientific Review Committee
    - IRB (Institutional Review Board)
  - Offers most easily accessible benchmarks for quality assurance assessment
  - Offers guidance for the treatment of the patient not treated on a clinical trial
The Relevant Clinical Process

• Clinical Evaluation
  – Determination of the local extent of tumor and relationship to normal tissue acquired from a number of diagnostic imaging sources
  – Staging
    • Charged particles are used for patients with M0 disease
  – Tumor board discussion
    • Treatment recommendation
    • Is patient eligible for an ongoing clinical study?
  – Presentation at particle rounds
Particle Rounds

• Relatively unique for particles
• Serves several very useful purposes
• Determination that particles offer a benefit over photons…i.e. triage
  – Charged particles are a limited resource
  – Charged particles are more expensive
  – Closely interfaced with the new patient intake process
• Held weekly at our institution
Particle Rounds

- **Discussion of the optimal target volumes**
  - Review of target volumes before planning
  - Review of treatment plan before fabricating patient specific hardware

- **Practical discussion**
  - Patient immobilization
  - Target volume expansion for intrafraction motion
  - Will photons be employed
    - Treatment planning system needs to handle photon and proton data?
Particle Rounds

- Can the patient who is medically appropriate be treated in a timely fashion?
  - Availability of a treatment slot
  - Per clinical trial guidelines
  - Per clinical data
    - Post-operative head and neck XRT within 6 weeks
    - Parameningeal rhabdomyosarcoma
      - If meningeal impingement (cranial nerve palsy, cranial base erosion, intracranial extension), XRT should start within 2 weeks
Intake Process

• Prioritization process: Who gets protons
  – Largest benefits for protons are likely for
    • Pediatric patients
      – At greatest risk for late effects
    • Larger fields
      – Will have the greatest volume of normal tissue spared by elimination of exit dose
    • Benign tumors
      – Patients most likely to live for a long period of time
    • Patients requiring higher dose
    • Patients not well treated by photons
      – Tumors adjacent to critical normal tissues
Intake Process

• Prioritization process for who gets protons
  – Children eligible for ongoing clinical studies
    • Other children
  – Adult patients not well treated by photons who are eligible for ongoing clinical studies
    • Large tumors
      – Including tumors large relative to the organ such as uveal melanoma
    • Near critical normal tissues
Intake Process

- Majority of patients currently treated with particles are referred from another institution
- To evaluate the patient appropriately, need:
  - Imaging data, both scans and reports
    - DICOM compatible to import into treatment planning system for fusion with planning CT scan
  - Clinical summary with clinical evaluation/treatment(s)
  - Pathology slides and reports for pathology review
  - Operative reports
  - Chemotherapy summary
  - Prior radiation records (if prior radiation therapy)
Patient Intake/Selection

• Establish list of patients/protocols to guide intake coordinators
• System to gather and screen patient intake materials
  – MD review ● Particle Rounds ● Patient accepted
  – Intake sheet to intake coordinator/scheduler
    • Treatment plan outline with # of photon/particle fractions
    • Immobilization parameters
    • CT simulation parameters (i.e. oral, iv contrast-? allergy)
    • Start date (i.e. if specific date mandated by research protocol, such as within 30 days of surgery)
Treatment Planning

• Immobilization devices compatible with both photons and particles
• Standardized acquisition of CT planning data
• PACS to push diagnostic scans to planning stations
• Treatment planning system that can integrate photon and particle treatment plans
Particle Rounds

- **Who attends**
  - Physicians
    - Medical Director and Associate Medical Director
    - Chief, Radiation Oncology
    - Clinical Director, Radiation Oncology
    - Physicians presenting new patients, reviewing XRT plans
  - Nursing
  - Chief dosimetrist
    - Other dosimetrists
  - Physics
  - Clinical Research Associates
On Treatment Quality Assurance

- **Patient treatment position verification**
  - Verification simulation first day of treatment
  - Pre-Rx orthogonal x-ray imaging prior to each fraction
    - Document intrafraction motion to allow adequate margins for treatment planning
  - Alternative imaging strategies
    - Out of room CT scans (per Paul Scherrer Institute)
    - Cone beam imaging
On Treatment Quality Assurance

• Adaptive therapy re-imaging
  – Defined plan for re-imaging the patient if gross disease that is expected to regress is present or if physiologic changes in normal tissue (i.e. mucus accretion in the sinuses) is anticipated
    • Cone beam in the treatment room
  – Adaptive re-planning
    • Likely to be more important for particles than photons
    • Deformable registration for contour propagation and dose mapping

• PET imaging of $^{11}$C and $^{15}$O
Documentation

- Electronic medical record
  - Consultation note with treatment recommendation
  - On treatment notes
  - Treatment summary
  - Document prescription
    - Standardized structure names facilitate data collection
  - Document treatment plan and plan review
  - Record dose
  - Archive for retrieval as needed
  - Data collection
Outcome Review

• **Treatment outcome review**
  - Local control
    - Site of local failure correlated with target volume(s) and dose prescribed
  - Regional control
  - Distant metastases
  - Overall Survival
  - Radiation related complications
    - Correlated with target volumes and dose prescribed
• **Comparison with published data**
• **Review data and discuss how to improve outcome**
Summary

• The quality assurance program and process in particle radiotherapy is quite similar to that of photons with need for quality assurance committee with written policies and procedures

  – Particle rounds conference facilitates the triage and treatment planning process and incorporates peer review into the evaluation of the patient from the start and engages other physicians, physicists, and dosimetrist into the determination of optimal treatment technique and target volumes
Summary

• Patient set-up and target volumes are monitored during treatment
  – Adaptive therapy strategies are likely to be more important for particles than photons

• Patient outcomes after treatment are monitored, assessed, and analyzed
  – Outcomes can be published
  – Outcomes should guide efforts to improve future treatment outcomes