High-Dose-Rate Intraoperative Radiation Therapy: The Nuts and Bolts of Starting a Program, and New Directions

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Disclosures

None
Outline

• Background
• JHH HDR-IORT Program
• Tips and Challenges
• New Directions

IORT Defined

• Intraoperative radiotherapy: a technique where a high, single fraction of radiation is delivered during a surgical procedure to a surgically exposed tumor or tumor bed while the normal tissues are protected from the radiation
Rationale for IORT

- Radiation therapy controls locoregional disease
- With improved systemic agents, local control becomes more important
- Higher radiation doses result in improved local control
- In many cases, total dose is limited by tolerance of adjacent normal structures

History of IORT

- Modern era began in 1960s after electron beam from linear accelerators became widely available, thus allowing for:
  - Excellent dose homogeneity
  - Rapid dose falloff
  - Control of depth of penetration
  - Rapid dose delivery
History of IORT (Cont’d)

• IORT given alone in large doses of 25-40 Gy to intact tumors → excessive morbidity, minimal improvement in survival
• Revival of interest in IORT driven by change in prescription paradigm
  – Now, routinely given as boost to moderate doses of EBRT and after surgical debulking → minimal morbidity and improved outcomes

Common Uses for IORT

• Malignancies with high risk for local recurrence in close proximity to radiosensitive structures:
  – Colorectal
  – Pancreatic
  – Gastric
  – Gynecologic
  – Retroperitoneal sarcomas
  – Head and Neck
  – Recurrent tumors
Advantages of HDR-IORT

- Direct visualization and thus greater accuracy in determining areas at risk
- Allows for movement and shielding of sensitive adjacent normal tissues
- Allows for re-treatment of previously irradiated recurrent tumors
- Eliminates delay between surgery and EBRT

JHH HDR-IORT Program

- November 2006
- Prior to program initiation, spent several weeks at existing IORT programs
- Patients selected based on established criteria during multidisciplinary consultations
Team

- Radiation oncology
  - Physicians, mid-level providers, residents
- Surgical oncology
  - Physicians, mid-level providers, residents
- Physics
- Anesthesia
- Nursing staff
- Coordinator

JHH HDR-IORT Safety Initiative

- Armstrong Institute for Patient Safety and Quality (AIPSQ) & Dr. Peter Pronovost
- Checklists
- Safety simulations
- Risk-assessment workshops
Scheduling of IORT

- The decision to perform IORT will need to be determined PRIOR to the surgery
- If IORT is needed during surgery, patient will need to be scheduled for a second surgery/IORT
- Intake form is completed (confirm what equipment is needed)
- Confirm billing codes needed for procedure
Scheduling of IORT

• Patient is seen in consultation by all disciplines
  – Is pre- or postoperative radiation needed?
  – Consent
  – Pre-operative clearance
• IORT coordinator determines optimal OR date with surgery, radiation oncology, anesthesia, and nursing
• OR date is scheduled, estimated time of HDR procedure determined (30 min–several hours)

Equipment

• OR - shielded and wired for HDR
• Afterloader - Nucletron microSelectron
• Planning system – Plato (now Oncentra Masterplan)
• Freiburg Flap*
• Catheters – 150 cm 6F Lumencaths*
• Stainless steel buttons*
• Lead sheets for organ shielding*

*Sterilized prior to procedure
Flap Prep Table

Timeline

Arrive in OR ----
Rad Onc
-- Assembles catheters, buttons, flap
--- Places Flap and Lead Shielding in patient

Radiation Oncologist consults with Surgeon and Physicist
--- Determines Rx “Parameters”

Physicist Oncentra planning

Rad Onc and Physicist
-- Review Oncentra planning
--- Check cable run
---- Treatment delivered

Physicist -- surveys patient
Rad Onc ---- removes flap and lead, etc
Flap in Position and Packed

Two-sided Treatment
Two-sided Treatment

Brachy Planning Process

- PLATO planning system (more recently Oncentra Masterplan)
  - Library plans of square flaps are recalled
  - Dwell positions are selectively added or deleted to match required shape and size
  - In small number of cases, catheter end positions are adjusted
Example Flap Geometry
Typical

Example Flap Geometry
Custom
Example Flap Geometry
Custom

Brachy Planning Process

• All plans are planar
  – Calculations demonstrate that dose varies less than 5% for flaps with radius of curvature greater than 3.7 cm
    • For Rx depth of 10 mm (5 mm into tissue)
  – “Only applies to Convex side of flap”
• Dose points are created at Rx depth for each dwell position
• Plan is Optimized and Prescribed to Dose Points
• Double check total time*activity/dose for area
Acceptable Flap Curvature

Un-acceptable Flap Curvature

Customized non-planar plans were created for select treatments
Conditions for Freiburg Flap

- Radius of curvature greater than 3.7 cm
- Backscatter material (i.e., wet towel) on flap minimum of 1 cm
  – (max effect no backscatter = –4%)
- Buttons are placed 10 mm from catheter tip
- Catheter off-set is 1494 mm for all catheters

Conditions for Lead Shielding

- Lead thickness of 3 mm produces about 50% attenuation
- Water equivalent material (~4 mm) between lead and tissue is needed to absorb excess electrons immediately below lead surface
- Lead sheets are wrapped in several layers of wet towels
Conditions for Lead Shielding

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<th>4 mm</th>
<th>8 mm</th>
<th>12 mm</th>
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<td>81%</td>
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JHH HDR-IORT Program – Results

- November 2006- May 2014
- 205 patients scheduled
- 122 (60%) patients treated & analyzed*
  - 48% sarcomas
  - 34% colorectal
  - 10% other GI
  - 8% GU
- Median OS = 35.7 months

*Includes primary and recurrent tumors
Case #1

• 35-year-old male undergoes resection of well-differentiated retroperitoneal sarcoma with negative margins and lymph nodes
• 7 months later: biopsy-confirmed liposarcoma → surgery + 12 Gy HDR-IORT → 45 Gy EBRT in 25 fx
• 3 years later: biopsy-confirmed liposarcoma outside of previous tx field → surgery + 12 Gy HDR-IORT → 39.6 Gy IG-IMRT in 22 fx
• 25-month f/u: doing well with no new recurrences

A) Freiburg flap is placed on the right lateral abdominal wall intraoperatively. Normal tissues were immobilized out of the radiation field. B) A HDR-IORT dosimetric plan showing 12 Gy prescribed to the to surface. Notice the sharp fall-off of dose with increased distance from the source.
### Case #2

- 38-year-old diagnosed with *moderately differentiated locally advanced rectal adenocarcinoma*
- Received neoadjuvant 5-FU + 54 Gy EBRT
- 3 months later: local progression → FOLFIRINOX
- 3 months later: further progression + bowel obstruction → colonic diversion
- 3 months later: 5-FU + 36 Gy EBRT + total pelvic exenteration + 12 Gy HDR-IORT
- 3 months later: determined to be MSI-H → gemcitabine + docetaxel RCT → MK-3475 RCT
- 5 months later: doing well

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A) Freiburg flap placed to cover the pelvis circumferentially following a pelvic exenteration. A 1-cm separation was used to limit overlap of the flap and prevent hotspots anteriorly. B) An HDR-IORT dosimetric plan showing 12 Gy prescribed to the surface.
Challenges to Consider

1. Good communication
2. IORT coordinator
3. Obtain relevant outside medical records and previous treatment summaries
4. Proper access and sterilization of all required equipment
5. All involved physicians and physicists present during the actual “beam on” time
6. Compliance with established safety protocols
7. Billing compliance using appropriate reimbursement codes

Mid-Level Providers in Radiation Oncology and Their Role in Brachytherapy

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Materials and Methods

- Literature review
- Medicare reimbursement guidelines
- AAPA/MD Board of Physicians credentialing
- AAPA census review
- Personal experience at JHU Dept. of Radiation Oncology

Need for Mid-Level Providers

- Increasing patient population in oncology and advancing technologies in radiation oncology
- Increased demand of assistance with procedural-based aspects of HDR-IORT
- Need improved workflow
  - Physician assistants (PAs) can perform procedures (IORT) under a licensed agreement
  - PAs can charge for brachytherapy services
Results

- 2010 AAPA census: Only 0.3% of PAs practice in Radiation Oncology and salaries are less than average

Results

- Practices can be reimbursed for 85-100% of physician fees for multiple brachytherapy CPT codes billed by PAs
- Applicator/Catheter Insertion/Implantation CPT codes
  - Multiple site codes: 20555, 22999, 47999, 49999, 49421, 45999, C9725
  - Daily insertion fee if multiple fractions
- Brachytherapy Setup Processes

*Equipment assessment and setup which can be performed by a credentialed PA.*
(A) Brachytherapy skin treatment setup, estimated simulation time: 3-4hr; (B) Typical IORT case, estimated equipment setup: 30-45mins; (C) Endorectal brachytherapy setup, estimated simulation time: 2.5hr, treatment day: 30-45mins.
Conclusions: Roles of PAs

- Emergent role of mid-level providers has been increasing in awareness and utilization in specialty clinics
- PAs can assist in improving patient treatment flow, provider workflow, and overall patient care and patient experience
- PAs can be cost effective and time efficient for Radiation Oncology departments
- PAs can help fill the deficit of increasing demand for experienced providers for brachytherapy procedures
- PAs can be an integral part of implementing clinical trials
- In an academic setting, establishing the role of PAs in brachytherapy technology can assist with resident training

Conclusions: HDR-IORT

- Proper planning, resources, and multidisciplinary collaboration needed
- Infrequent utilization of IORT is likely due to lack of awareness, physician experience, and access
- Additional programs will likely increase the likelihood of durable local control for patients with advanced or recurrent tumors
New Directions

- Novel chemotherapy or targeted agents
- Combination of SBRT/SABR and HDR-IORT
- Amifostine and HDR Small et al. Int J Gynecol Cancer 2011
  - RTOG 0116: cisplatin, amifostine, EBRT, IORT in cervical cancer
- Dynamic rotating shield HDR-IORT Liu et al. Med Phys 2013
  - Can boost tumor while minimizing toxicity
  - Less invasive plans with better dose distribution

Collaboration: Thank You

- During implementation:
  - H. Malhotra, PhD, M. Podgorsak, PhD and W. Jaggernauth, MD
  - Roswell Park Cancer Institute
  - Mayo Scottsdale/Len Gunderson, MD
- Johns Hopkins Radiation Oncologists/Physics
  - Drs. Herman, Frassica, Zellars, Asrari, Wharam
  - Woody Armour, Yi Le
- Johns Hopkins Surgeons
  - Drs. Ahuja, Gearhart, Terezakis, Pawlik, Efron, Weber, Eckhauser, etc. (22 total)
- Johns Hopkins Anesthesia
  - Drs. L. Mark, Rodriguez-Paz, Pronovost
Thank You!