Advances in Permanent Seed/Source Implantation (PSI) Brachytherapy

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Room: Track 5

DISCLOSURES

• Mourtada: ABS President 2020-2021
• Rivard: research grants from Isoray, Bard, CivaTech
• Podder: None
LEARNING OBJECTIVES

Mourtada:
1. Understand the fundamentals of prostate PSI program quality and safety

Rivard:
2. Learn various techniques used for PSI in different anatomical sites

Podder:
3. Understand the importance of application of multi-modal imaging in PSI
4. Learn the new and advanced methodologies available for PSI

1st Talk LEARNING OBJECTIVES

1. Review the basic concepts for starting a permanent prostate seed program

2. Discuss how a comprehensive QM program can help to ensure quality and safety
PSI for Prostate

Low Dose-Rate and Low Energy Sources

- Dose Rate is 0.07-0.3 Gy/h
- Energy <50 keV
- Commonly used:
  - I-125, Pd-103
  - Most recent: Cs-131

Radionuclide Selection

<table>
<thead>
<tr>
<th></th>
<th>Half Life (days)</th>
<th>Time to deliver 90% dose (days)</th>
<th>Mean Energy (kV)#</th>
<th>Half Value Layer (μm Lead)*</th>
<th>Monotherapy Rx (Gy)</th>
<th>BED (Gy)**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cs-131</td>
<td>9.7</td>
<td>33</td>
<td>29</td>
<td>26</td>
<td>115</td>
<td>112</td>
</tr>
<tr>
<td>I-125</td>
<td>59.4</td>
<td>204</td>
<td>27</td>
<td>21</td>
<td>145</td>
<td>111</td>
</tr>
<tr>
<td>Pd-103</td>
<td>17.0</td>
<td>58</td>
<td>23</td>
<td>8</td>
<td>125</td>
<td>115</td>
</tr>
</tbody>
</table>

- #https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2807139/
- *https://www.doseinfo-radar.com/Exposure_Rate_Constants_and_Lead_Shielding_Values%204.pdf
"Quality cannot be copied; there is no step-by-step cookbook that applies equally to all company situations and cultures."

Ernst & Young

What is Quality Management Program (QMP)?

- Formalized program that documents processes, procedures, and responsibilities for achieving quality policies and objectives.
- QMP helps coordinate and direct organizational activities to meet customer (patient) and regulatory requirements, and improve its effectiveness and efficiency on a continuous basis.
- Example: ISO 9001:2015, the international standard specifying requirements for quality management systems, is the most prominent approach to quality management system.

https://asq.org/quality-resources/quality-management-system
Why you need a QMP for prostate brachytherapy

“Increasingly apparent that efficacy surrogates such as biochemical relapse-free survival and morbidity are dependent on implant quality”

Read more:

Implementing a QMP for your brachy program

1. Design: Multidisciplinary team/Fishbone diagram
2. Build: Order equipment/write policies and SOPs
3. Deploy: Commission/End-to-End tests
4. Control and Measure: Quarterly Audits
5. Review and Improve

The Plan-Do-Check-Act (PDCA) Cycle

Allows for continuous improvement to both implant quality and the QMP

https://asq.org/quality-resources/pdca-cycle
CQI- Continuing Quality Improvement

The Medical Director of Radiation Oncology is responsible for the institution and ongoing supervision of continuing quality improvement (CQI) as described in the ACR–ASTRO Practice Parameter for Radiation Oncology [16]. It is the responsibility of the Director to identify problems, see that actions are taken, and evaluate the effectiveness of the actions. The Director will designate appropriate personnel to constitute the CQI Committee that will review LDR brachytherapy as part of the CQI meeting agenda. Refer to the ACR–ASTRO Practice Parameter for Radiation Oncology [16] for a detailed description of CQI Committee functions.

https://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards/Practice-Parameters-by-Subspecialty

12 elements of an LDR prostate BT QMP

1. Written Directive
2. Patient Consultation
3. Seed Order, Receipt and Assay
4. Case Preparation
5. Confirmation of Patient Identity
6. QA Steps in administration of radioactive seeds
7. Recovery and Discharge
8. Confirmation of dosage and Medical Event Procedure
9. Waste Disposal (Decay-in-Storage)
10. Return seeds to vendor for cancelled cases
11. Program periodic review (internal independent audits)
12. Initial then annual staff training

Excellent place to start is NRC 10 CFR, Part 35
Commissioning your PSI program

Process by which an equipment, or facility (which is installed, or is complete or near completion) is tested to verify if it functions according to its design objectives or specifications.

Read more: http://www.businessdictionary.com/definition/commissioning.html
Commissioning Elements

Commissioning is the first element of the overall Quality Management Program to reduce/prevent:

- Hardware failures
- Software failures
- Human failures
- Organizational failures

Step 1: Review Consensus Literature
Published Guidelines

- ABS Consensus Guidelines for PSI
  https://www.americanbrachytherapy.org/consensus-statements/prostate/
- AAPM TG-40: Comprehensive QA for radiation oncology
- AAPM TG-43: Dosimetry of interstitial brachytherapy sources
- AAPM TG-53: Quality assurance for clinical radiotherapy treatment planning
- AAPM TG-56: Code of practice of brachytherapy physics
- AAPM TG-64 Permanent prostate seed implant brachytherapy
- AAPM Report 98: Third-party source calibrations and physicist responsibilities
- AAPM TG-128: Ultrasound imaging quality assurance
- AAPM TG 137: Recommendations on dose prescription and reporting methods for permanent interstitial brachytherapy for prostate cancer
- ESTRO WP12: Recommendations for QA of ultrasound imaging in brachytherapy
- ACR: Technical Standards and Practice Parameters
  https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Brachy-Prostate.pdf
  https://www.acr.org/-/media/ACR/Files/Practice-Parameters/LDR-BrachyTS.pdf

Step 2: Establish a clinical workflow
Two Common Planning Approaches

- Simulate and Plan day(s) before the implant (**preplanning approach**)
  - Preplanning approach: decrease in OR time and costs as well as a decrease in stress on the implant team.
- Simulate and Plan immediately prior to the implant procedure (**intraoperative approach**).

Basic Workflow Elements (Pre-plan Approach)
Design Phase: Use Fish-bone diagrams

Two pt identifiers, done in the OR

We learned other factors:
✓ Before anesthesia,
✓ check all team members arrived,
✓ Seeds in OR, sterile packaging intact
✓ WD 145Gy or 110Gy

OR Layout for Prostate PSI

Bruce Thomadsen, Ph.D.
Step 3: Imaging and TPS QA

Physics factors impacting LDR prostate implants clinical outcome quality

1. Image modality fidelity (CT/MR/US)
   - ROI contouring accuracy

2. Seed localization accuracy
   - LDR TG-43 data input accuracy

3. Dose model assumptions
   - Source decay in TPS, etc.

Clinical Outcome Quality
AAPM TG-53: QA for Radiotherapy Treatment Planning

1. Image Import
2. Registration
3. Contouring
4. Dose Calculations (TG-43)
5. Plan Evaluation
   - Dose displays
   - DVH
   - Printout accuracy

Joint AAPM/IROC Houston Registry of Brachytherapy Sources Meeting the AAPM Dosimetric Prerequisites

<table>
<thead>
<tr>
<th>Source Registry</th>
<th>Application for Registry</th>
<th>Registry Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prerequisites</td>
<td>Dosimetry Datasets</td>
<td>Model-Based Dose Calcs</td>
</tr>
<tr>
<td>AAPM Publications</td>
<td>3rd Party Checks</td>
<td>Disclaimer</td>
</tr>
</tbody>
</table>

| LDR 125 I Sources |  |  |
|-------------------|--------------------------|
| Manufacturer      | Sources                  | Model              |
| BB&G Co.          | IsoSeed I-125            | 125.S17 plus       |
| Best Medical      | I-125                    | 2301               |
| International     |                          |                    |
| Inc.              |                          |                    |
| Bard Urological   | 155 Implanted Seeds      | STM1251            |
| Division           |                          |                    |
| IsoAid, LLC       | Advantage I-125          | 142-125A           |
| Nuketeron         | selectSeed I-125         | 130.002            |
| Theragenics       | I-Seed I-125             | Agi100             |

| LDR 131 Cs Sources |  |  |
|-------------------|--------------------------|
| Manufacturer      | Sources                  | Model              |
| IsoRay Medical    | Procelean                | CS-1 Rev2          |

http://rpc.mdanderson.org/RPC/BrachySeeds/Source_Registry.htm
AAPM TG-128: US Imaging QA

Table II. Quality control tests: frequencies and action levels.

<table>
<thead>
<tr>
<th>Test</th>
<th>Minimum frequency</th>
<th>Action level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grayscale visibility</td>
<td>Annual</td>
<td>Change &gt;2 steps or 10% from baseline</td>
</tr>
<tr>
<td>Depth of penetration</td>
<td>Annual</td>
<td>Change &gt;1 cm from baseline</td>
</tr>
<tr>
<td>Axial and lateral resolution</td>
<td>Annual</td>
<td>Change &gt;1 mm from baseline</td>
</tr>
<tr>
<td>Axial distance measurement accuracy</td>
<td>Annual</td>
<td>Error &gt;2 mm or 2%</td>
</tr>
<tr>
<td>Lateral distance measurement accuracy</td>
<td>Annual</td>
<td>Error &gt;3 mm or 3%</td>
</tr>
<tr>
<td>Area measurement accuracy</td>
<td>Annual</td>
<td>Error &gt;5%</td>
</tr>
<tr>
<td>Volume measurement accuracy</td>
<td>Annual</td>
<td>Error &gt;5%</td>
</tr>
<tr>
<td>Needle template alignment</td>
<td>Annual</td>
<td>Error &gt;3 mm</td>
</tr>
<tr>
<td>Treatment planning computer volume</td>
<td>Acceptance testing</td>
<td>Error &gt;5%</td>
</tr>
</tbody>
</table>
Step 4: Radiation Safety, Staff Training, Patient Education

Regulatory responsibilities must be defined in QMP

- Licensing
- TPS QA and Dose 2nd check
- Survey meter QA
- Source receipt and tracking
- Source assays
- Patient surveys and release criteria
- Written Directives
- Written Procedures
Radiation Surveys

1. Patient
   - Survey patient before and after implant at one meter (~3 ft)
   - Document patient, survey meter, survey result, and survey staff in accordance with state/federal regulations

2. Room
   - Survey procedure room, personnel leaving OR, instruments, patient table, urine bag, needle bin, trash

PSI Staff Training
- Describe general sealed source brachytherapy applications
- Introduce radiation safety concepts
- Describe PSI patient release methods (NRC Rulings)
Records

• Maintain records for 3 years
  • Written Directives
  • Source tracking, assays, surveys
  • Procedures and QA

Continuous Quality Improvement (CQI) Team

✓ AU
✓ RSO
✓ Medical Physicist
✓ Clinical Director
✓ OR Nursing Manager
✓ Scheduler
CONCLUSIONS

• High-quality QMP elements are drivers toward superior patient outcomes.
• QMP should be dynamic with continual improvement cycle.