EXPERIENCE WITH TG-100 IN CLINICAL USE HDR BRACHYTHERAPY

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Disclosure
- I have no disclosures

Objectives
- Learn how to characterize HDR brachytherapy for risk assessment and clinical use
- Be able to identify potential failure modes for HDR brachytherapy procedures and learn mitigation techniques
- Understand a FMEA example of GYN HDR brachytherapy
TG-100 clinically stated
- Focus on prospective error management techniques
- Workflow processes to target human error
- Site specific, modality driven quality measures within a dept

GYN Brachytherapy Evolves
- Sophisticated imaging modalities in radiation oncology departments, the use of image-guided gynecologic brachytherapy planning is increasing
- Focusing on operational efficiency, safe and streamlined workflow processes can be implemented
- In 2008, the American Brachytherapy Society published a practice patterns survey regarding three-dimensional (3D) imaging in gynecologic brachytherapy (1)
- ABS update MRI guidance in cervical cancer is now about 31% based on 4 questions

Image Guided Brachytherapy
- GEC-ESTRO guidelines
- Dose escalation

Potters, Radiotherapy and Oncology, 7/2011;100(1):116-123
Image Guidance – Incorporation of MRI based planning

MRI Based Planning
- Do we really need MRI based image guidance for all brachytherapy cases?
- MRI more appropriately assesses tumor size and shape compared to clinical examination and CT-scan. 
- Improved local control, decreased morbidity, and seemingly higher survival rates with MRI guided brachytherapy.

CT Based Planning
- Gimbok Vishwathan et al. 2014, showed no difference in dosimetric coverage of the tumor (D90) from implementing MRI before CT-based brachytherapy or from using MRI during brachytherapy.
- Chino et al. 2014, abstract showing that MRI based planning on each fraction was not superior to CT based OAR optimization.

Risk Assessment
- High importance in HDR brachytherapy
- Collaborative team approach
- Improve quality assurance
- Reduce near miss or reportable events

HDR Brachytherapy Workflow
- Complex multistep process
- Clinical assessment and procedure
- Sedation, critical care of the patient
- Image Guidance – procedure, imaging, treatment planning
- Treatment planning
- Treatment
How long does the IGBT process take?
• During 2010-2012, 217 tandem and ring brachytherapy procedures were consecutively performed at our institution on 52 patients with locally advanced cervical cancer.

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<th>needles</th>
<th>injection</th>
<th>treatment time</th>
<th>treatment day</th>
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<th>Total time</th>
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</tbody>
</table>


Process Options
• Modern error prevention tools place emphasis on process flows and expected actions based on graphical or visual representation
  • Processes
  • FMEA
  • Process flow maps
  • Fault tree analysis

FMEA of HDR GYN brachytherapy
• Goal: represent our process steps to further identify and recognize potential risk, redundancy, bottlenecks, and constraints in our workflow
• Concentrated on the scores with the highest value to target operational changes and improvements in our workflow
• Used an example of tandem and ring brachytherapy for locally advanced cervical cancer
FMEA approach

- Question is broken into individual steps and analyzed
- Each step through the implementation of the technique
- All potential modes of failure are identified, along with the possible causes
- Failure mode (FM) is ranked in three categories: (1) the probability of occurrence, (2) the severity of possible consequences if the failure is not detected, and (3) the ability to detect the failure itself.

FMEA Strategy

- Pull all team members into a room
- Identify each process, subprocess
- Think of everything that could go wrong with each step – these are your failure modes
- Met 6 times, once per month

Risk Priority Number

- A score from 1 to 10 is given to each quantity of probability, severity, and detectability.
- These three values are then multiplied together to determine a risk priority number (RPN).
- Use the highest RPN to prioritize the direction of the quality assurance program
- Made our own 10 pt scoring system
Occurrence

Mayadev et al. Brachytherapy 2015

Detectability

Results

- Identified 170 FM
- 99 were scored
- RPN scores ranged from 1 to 192
- Of the 13 highest-ranking FMs with RPN scores >80, half had severity scores of 8 or 9, with no mode having severity of 10.
Results

- Scores 1-192; top 2 had values 192
- Took the top 13 RPN, with scores >80%

Mayadev et al, Brachytherapy 2015

Results

- Of these FM, the originating process steps were simulation (5), treatment planning (5), treatment delivery (2), and insertion (1).
- Our high-ranking FM focused on communication and the potential for applicator movement.
- Evaluation of the efficiency and the comprehensiveness of our quality assurance program showed coverage of all but three of the top 49 FMs ranked by RPN.

FM detailed with severity of 9
Examining FM w high RPN

• (1) Failure to inform dosimetry (O = 4, D = 6, S = 8, and RPN = 192)

• (2) Not finding an existing error during the physics plan check (O =2, D =10, S =8, and RPN = 160)

• 3 FM did not have a QA check : above and incorrect imaging protocol during sim

Changes to our clinical practice

• Identify systemic vulnerability

• Added a checklist “baton” for timestamp and physical movement

• Added step in existing checklist for applicator movement

• Encouraged to look deeper into our treatment planning subprocess

Targeting the Treatment Planning Time

<table>
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<tr>
<th></th>
<th>MD notification to start review</th>
<th>MD planning time</th>
<th>Dose received before plan ready to check</th>
<th>Physics planning time</th>
<th>Overall time</th>
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<tr>
<td>Median</td>
<td>48</td>
<td>67</td>
<td>20</td>
<td>7</td>
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<td>Mean</td>
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<td>68</td>
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<tr>
<td>Stddev</td>
<td>14</td>
<td>6</td>
<td>8</td>
<td>6.5</td>
<td>19</td>
</tr>
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</table>

Formed a brachytherapy handoff checklist with initials and timestamp
Your specific optimal workflow

- Each site self exploration
- Target the implant time, or treatment planning time
- Quarterly workflow meetings to interface with our brachytherapy team
- Select specific brachytherapy therapists or dosimetrists
- Identify critical components for skillful coordination
- In room image guided brachytherapy suites