EXPERIENCE WITH TG-100 IN CLINICAL USE HDR BRACHYTHERAPY

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Diclosure

- 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

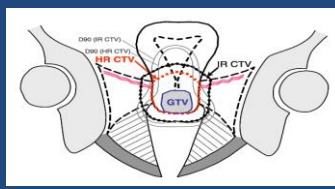
- Focus on prospective error management techniques
- Workflow processes to target human error
- Site specific, modality driven quality measures within a dept

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[2,3]
- Improved local control, decreased morbidity, and seemingly higher survival rates with MRI guided brachytherapy[4,5]

CT Based Planning

- Cimbak, 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.

Descriptive statistic	Preoperative time[1]	Insertion[2]	Imaging[3]	Insertion finish to treatment[4]	Treatment planning[5]	Treatment and recovery[6]	Total clinic[7]
Implant number	212	214	214	209	210	208	207
Minimum	30	5	3	87	43	9	230
25% Percentile	63.3	14	23	147	111	79.3	355
Median	78	20	30	170	133	112.5	395
75% Percentile	110	28	45	208	155	141	435
Maximum	293	120	279	407	265	287	720
Mean	94	22.6	45.2	181.5	137.5	114.8	401.1

Mayadev et al. *Brachytherapy* 13 (2014), 233-239

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

J. Mayadev et al. / Brachytherapy – (2015)

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.

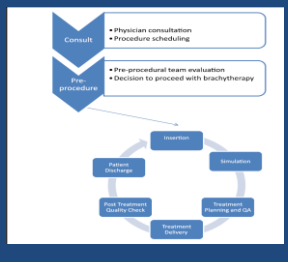
FMEA Strategy

- 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

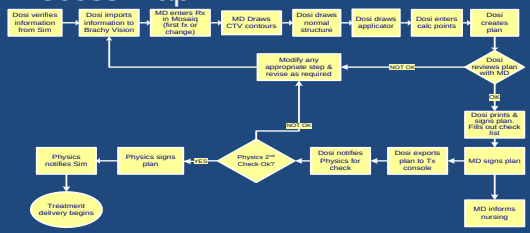
Risk Priority Number

- 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

Process Tree



Process Map



Treatment Planning and QA Sub-process

Severity

Score	Find[1]	Risk[2] Qualitative	Categorization	Serious[3]	Davis[4]	UC Davis
1	No effect	No effect		No adverse event	None at all	No effect
2	& Dose 5%	Inconvenience	Inconvenience	Grade 1: mild; asymptomatic or mild symptoms; intervention not indicated		& Dose <7%; min or no effect; no intervention
3	& Dose 5%	Inconvenience	Inconvenience	Grade 1: mild; asymptomatic or mild symptoms; intervention not indicated		
4	Min delay in care	Minor dosimetric error	Suboptimal plan or tx	Grade 2: moderate; minimal intervention; limiting instrumental activities of daily living	(Moderate—significant effect with no injury)	& Dose 5–10%; moderate symptoms; minimal intervention
5	Min delay in care	Limited toxicity or tumor underdose	Wrong dose, dose distribution, location, or volume	Grade 2: moderate; minimal intervention; limiting instrumental activities of daily living		
6	Allergic rx; moderate delay in care	Limited toxicity or tumor underdose	Wrong dose, dose distribution, location, or volume	Grade 3: severe or medically significant but not immediately life threatening; hospitalization; disabling; limiting self-care		& Dose 10–20%; severe/ medically significant, bleeds, and no death required
7	Allergic rx; moderate delay in care	Potentially serious toxicity or tumor underdose	Wrong dose, dose distribution, location, or volume	Grade 3: severe or medically significant but not immediately life threatening; hospitalization; disabling; limiting self-care	(Major injury)	
8	& Dose 20%; reportable		Wrong dose, dose distribution, location, or volume	Grade 4: life threatening; urgent intervention indicated		& Dose ≥ 20%; reportable; life threatening, urgent intervention
9	& Dose 20%; reportable	Possibly very serious toxicity or tumor underdose	Very wrong dose, dose dist., location, or vol.	Grade 4: life threatening; urgent intervention indicated		
10	Patient dies	Catastrophic	Very wrong dose, dose dist., location, or vol.	Patient death	Death	Death

Mayadev et al. Brachytherapy 2015

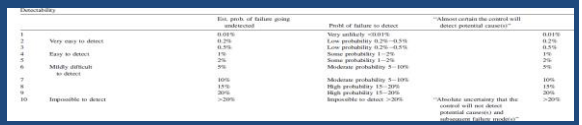
Occurrence

Occurrence

		Qualitative	Frequency			
1	Less than every 5 yrs	Failure unlikely	1/10,000 (0.01%)	Very unlikely <0.01%	Failure is unlikely 1 in >5 yrs	Less than 1/yr
2	Every 2–5 yrs	Failure unlikely	2/10,000 (0.02%)	Low probability 0.02–0.04%		Once/yr
3	Once/yr	Relatively few failures	5/10,000 (0.05%)	Low probability 0.02–0.04%		2–3 times/yr
4	Several times/yr	Relatively few failures	1/1000 (0.1%)	Some probability 0.05–0.4%		Once/every 2 mo
5	Once/mo	Relatively few failures	<0.2%	Some probability 0.05–0.4%		Once/mo
6	Several times/mo	Occasional failures	<0.5%	Moderate probability 0.5–1%		2–3 times/mo
7	Once/wk	Occasional failures	<1%	Moderate probability 0.5–1%		Once/wk

Mayadev et al. Brachytherapy 2015

Detectability



Detectability

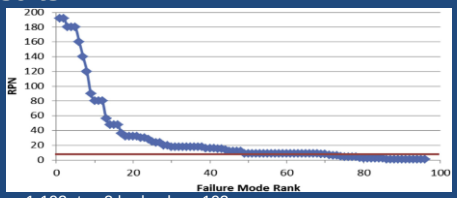
		Est. prob. of failure going undetected	Probt of failure to detect	"Almost certain the control will detect potential cause(s)"
1		0.01%	Very unlikely <0.01%	0.01%
2	Very easy to detect	0.2%	Low probability 0.2%–0.5%	0.2%
3		0.5%	Low probability 0.2%–0.5%	0.5%
4	Easy to detect	1%	Some probability 1–2%	1%
5		2%	Some probability 1–2%	2%
6	Mildly difficult to detect	5%	Moderate probability 5–10%	5%
7		10%	Moderate probability 5–10%	10%
8		15%	High probability 15–20%	15%
9		20%	High probability 15–20%	20%
10	Impossible to detect	>20%	Impossible to detect >20%	>20%

"Absolute uncertainty that the control will not detect potential cause(s) and subsequent failure mode(s)"

Results

- Identified 170 FM
- 99 were scored
- RPN scores ranged from 1 to 192
- Of the13 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%

Mavadev 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

FM with a severity of 9

Subprocess	Step	Failure mode	Failure effects	Likelihood of occurrence 1–10	Likelihood of nondetection 1–10	Severity 1–10	Risk priority number (RPN)	Number of quality assurance checks
Tx planning	Physics check	Not detecting errors	Incorrect dose distribution	2	10	9	180	0
Tx planning	Source exchange	Incorrect activity entered at source exchange and entered into decay table	Incorrect dose distribution	1	10	9	90	1
Treatment delivery	Connect guide tube to afterloader	Incorrect channel	Incorrect dose distribution	2	2	9	36	3
SIM	Routine morning quality assurance	Not performed	Incorrect dose delivered	2	1	9	18	1
Insertion	Transport—GYN table to gantry	Patient falls	Patient injury	2	1	9	18	2
SIM	Transfer—gantry to sim table	Patient falls	Patient injury	2	1	9	18	2
SIM	Transport	Patient falls	Patient injury	2	1	9	18	2
Treatment delivery	Plan printout	Plan report vs. plan not verified	Incorrect dose delivered	1	2	9	18	1
Treatment delivery	Plan printout	Treatment console decay incorrect	Incorrect dose delivered	2	1	9	18	4
Treatment delivery	MD verifies plan	Treatment console decay incorrect	Incorrect dose delivered	1	2	9	18	3
Treatment delivery	PhD verified plan	Treatment console decay incorrect	Incorrect dose delivered	1	2	9	18	3

Examining FM w high RPN

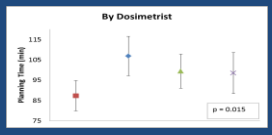
- (1) Failure to inform dosimetry (O = 4, D = 6, S = 8, and RPN = 192)
- (2) Not finding an existing error during the physics plan check (O =2, D =10, S =8, and RPN = 160)
- 3 FM did not have a QA check : above and incorrect imaging protocol during sim

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

	Dosi planning time	MD notification to start review	MD planning time	Dosi notifies physics plan ready to check	Physics starts to review plan	Physics planning time	Overall time
Mean	43	6	20	10	7	13	96
Median	40	4	18	9	5	11	94
MIN	17	0	9	0	0	2	64
MAX	86	27	60	26	30	45	145
Stddev	14	6	8	6	7	7	19



Formed a brachytherapy handoff checklist with initials and timestamp

Michaud, Mayadev, Brachytherapy 2016 press

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