Stereotactic Ablative Radiotherapy (SAbR): Opportunities and Pitfalls

Timothy D. Solberg, Ph.D.
Barbara Crittenden Professor of Cancer Research
Director, Division of Medical Physics and Engineering
Department of Radiation Oncology
University of Texas Southwestern Medical Center
Timothy.solberg@utsouthwestern.edu

DISCLOSURES

Industry Research Funding and/or Support:
- Accuray
- Calypso
- Elekta
- Philips
- Varian
- VisionRT

Ownership:
- Global Radiosurgery Services, LLC

50+ years of technology development and clinical application established SRS as a successful therapy

Technically, this guy is my boss …..
50+ years of technology development and clinical application established SRS as a successful therapy.

And motivated technology and clinical application to extracranial sites.

Mehta et al, IJROBP 49:23-33, 2001

“If higher doses can be delivered to limited volumes using advanced conformal techniques such as IMRT gated for breathing, together with on-line verification and adaptation, large increases of local control would be expected.”

Mehta et al, IJROBP 49:23-33, 2001
**Indiana Phase I**

47 patients with medically inoperable NSCLC

Dose escalated from $3 \times 8$ Gy to $3 \times 24$ Gy

MTD ($< 5$ cm) was not reached

MTD ($> 5$ cm) $\sim 66$ Gy

Timmerman et al, J Thoracic Onc, 2007

---

**Indiana Phase II**

70 patients with medically inoperable NSCLC

$> 5$ cm: $3 \times 20$ Gy  
$< 5$ cm: $3 \times 22$ Gy

$< 20\%$ Grade 2+ toxicity

Risk of Grade 3+ toxicity 11 times greater for centrally located tumors

Timmerman et al, J Thoracic Onc, 2007

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**RTOG 0236**

A Phase II Trial of Stereotactic Body Radiation Therapy (SBRT) in the Treatment of Patients with Medically Inoperable Stage III Non-Small Cell Lung Cancer

**SCHEMA**

**Stereotactic Body Radiation Therapy (SBRT), 20 Gy per fraction for 3 fractions over 1.5 weeks, for a total of 60 Gy**

**Qual趁着 Volume Dose (Gy)**

- **Spinal Cord**
  - Any point: $16$ Gy
  - Any point: $16$ Gy per fraction

- **Esophagus**
  - Any point: $22$ Gy
  - Any point: $22$ Gy per fraction

- **Ipsilateral Bronchus**
  - Any point: $24$ Gy
  - Any point: $24$ Gy per fraction

- **Heart**
  - Any point: $20$ Gy
  - Any point: $20$ Gy per fraction

- **Trachea and Ipsilateral Bronchus**
  - Any point: $10$ Gy
  - Any point: $10$ Gy per fraction

- **Whole Lung (Right & Left)**
  - See table in Section 4.4.2
  - See table in Section 4.4.2

**Lung volume receiving 20 Gy or more ($V_{20}$) must be less than 10%, (or less than 15% for minor deviation)

Timmerman et al, JAMA, 2010

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**RTOG 0236**

**Stereotactic Body Radiation Therapy for Inoperable Early Stage Lung Cancer**

Robert Timmerman, MD
Rebecca Poelke, MD
James Salem, MD
Jeffery Mechanic, MD
William McLaughlin, MD
Jeffrey Reck, MD
John Ferris, MD
Susan Hendry, MD
Gregory Yuksekdag, MD
David Johnson, MD
Jack Yarnold, MD
Elizabeth Care, MD
Rick O'Connor, MD

**Control**

Patients with early-stage but medically inoperable lung cancer have a poor rate of primary tumor control (20%-40%) and a high rate of mortality (50% within 1 year). Dose escalation is a straightforward means of improving outcomes.

**Objective**

To evaluate the feasibility and efficacy of stereotactic body radiation therapy in a randomized, prospective study of patients with early-stage but medically inoperable lung cancer.

**Design, Setting, and Patients**

Phase II National Cancer Institute of Canada trial conducted at 46 centers across North America. Patients were aged 16 years or older with non-small cell lung cancer of any stage. Patients with prior surgery were excluded. The primary outcome was freedom from local-regional failure, defined as freedom from local-regional recurrence or distant metastasis at 3 years.

**Randomization and Measurements**

The primary end points were 2-year actuarial freedom from local-regional failure, freedom from systemic failure, overall survival, and treatment-related toxicity. Treatment-related toxicity was assessed using the Common Terminology Criteria for Adverse Events version 3.0.

**Results**

A total of 153 patients were assigned to the 2 treatment arms: the 50 Gy arm ($N = 77$) and the 60 Gy arm ($N = 76$). The 2-year actuarial freedom from local-regional failure rates were $75\%$ and $54\%$, respectively. There was no difference in overall survival rates between the 2 arms, with 2-year actuarial survival rates of $83\%$ and $76\%$, respectively.

**Conclusion**

Patients with medically inoperable non-small cell lung cancer who received stereotactic body radiation therapy had an excellent rate of primary tumor control and moderate treatment-related mortality.

Timmerman et al, JAMA, 2010
RTOG 0236

59 IA / IB patients accrued
55 eligible for follow up
3 year actuarial control 97.6%
(1 local failure)
3 year DFS 48.3%; 3 year OS 55.8%
Median OS 48.1 months
7 grade 3 events / 2 grade 4 events

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Median OS 48.1 months
7 grade 3 events / 2 grade 4 events

5 year local control 86.7%
92.0% (IA) / 73.0% (IB)
5 year Survival 69.5%
72.0% (IA) / 63.2% (IB)

57 NSCLC patients 45 Gy in 3 fractions
3 year Local Control 92%
88% Cancer Specific Survival @ 3 years
16 patients w/ grade 3 toxicity
1 patient w/ grade 4 toxicity

38 patients with 63 lesions
48 – 60 Gy in 3 fractions
100% Local Control @ 1 year
96% Local Control @ 2 years
19 month median survival
3 patients w/ grade 3 toxicity
No patients w/ grade 4-5 toxicity
Phase I/II SBRT trial for liver mets

Dose escalation to 60 Gy in 3 fractions
47 patients
Local control 95% & 92% at 1 & 2 years
1 Grade 3 toxicity

Pre-SBRT
6 mo
Post-SBRT

Rustoven et al, JCO, 2009

But with any aggressive approach, there may be complications

Three treatment-related deaths following SBRT for primary liver cancer
3 x 15 Gy for 57 cc tumor
3 x 10 Gy for 293 cc tumor
1 x 30 Gy for a “large” tumor


And there is a significant burden on practitioners to minimize errors

In 1997, between 44,000 and 98,000 patients died as a result of medical errors
- To Err is Human: Building a Safer Health System, Institute of Medicine

Dose Response to Spine SRS

91 lesions in 79 patients
Prescribed 18-24 Gy
Cord constrained to 14 Gy

Dose > 15.1 Gy

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- To Err is Human: Building a Safer Health System, Institute of Medicine
Our profession has certainly seen its share of errors

For many of us, the awareness began with this series of articles

But accidents and the publicity surrounding them are nothing new
At least 40 people killed and the NRC doesn’t know it

PART 1, Published Dec. 13, 1992 — Sloppy radiation therapy procedures in America’s hospitals have killed at least 40 people and maimed dozens of others. The U.S. Nuclear Regulatory Commission, the agency primarily responsible for protecting the public from radiation mishaps in medicine, can’t name a single fatality. Pages 3, 4.

The spill that shook the Cleveland Clinic

PART 2, Published Dec. 14, 1992 — A series of blunders at the Cleveland Clinic in May 1991 led to a record third NRC fine and prompted a top clinic official to call the institution’s safety program an embarrassment. Pages 5, 6.

The nation’s worst disaster — it happened in Ohio

PART 3, Published Dec. 15, 1992 — The nation’s worst radiation therapy disaster occurred at Eirexide Methodist Hospital in Columbus in 1975-76. Although more than 20 people received radiation overdoses and at least 12 died, the NRC’s medical consultant shut down his inquiry because he didn’t want to embarrass the hospital. Pages 7, 8.

Several responses to congressional hearings

SUMMARY

1 INTRODUCTION
   Errors and inaccuracy, Benefits and Problems of Radiation Medicine
   The Current Regulatory System
   The System of Medical Study
   Chapter Summary

2 CLINICAL APPLICATIONS OF IONIZING RADIATION
   Measures of Patient Exposure to Ionizing Radiation
   Diagnostic Applications of Ionizing Radiations
   Therapeutic Applications of Ionizing Radiations
   Chapter Summary

3 REGULATION AND RADIATION MEDICINE
   Regulatory Goals
   The Current Regulatory Framework
   The Concept of NRC Regulations
   Quality Assurance of NRC Regulations
   Chapter Summary

4 RISKS OF IONIZING RADIATION IN MEDICINE
   Risk Assessment

and the reaction should be predictable ……

Human tragedies, official coverups, government laxity

PART 4, Published Dec. 16, 1992 — Jean Matalka doesn’t show up in NRC records as a radiation therapy casualty because she took her own life after her doctor burned a hole in her chest. Neither does Stella Johnson, even though a radiation overdose killed her. They are among hundreds of people who are overdosed in our nation’s hospitals each year. Pages 9-11.

Lies, deceit, convictions — and nobody’s in jail

PART 5, Published Dec. 17, 1992 — NRC investigators have caught dozens of hospital officials lying, falsifying records and covering up radiation overdoses. Yet only three people have been convicted of crimes and no one has ever gone to jail. Some still work at the same hospitals. Pages 11, 12.

A promise from NRC, hearings before Congress

FOLLOW-UPS, Published Dec. 19-20, 1992 — After reading the Plain Dealer series, NRC Chairman Ivan Selin promised major reforms in the agency’s medical licensing and inspection programs. Sen. John Glenn and Rep. Michael I. Synar also announced that congressional investigations would focus on the NRC’s findings. Pages 12, 13.

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Who caught it, and what could have been done to prevent it?

Patients “caught” it

Better training on SRS principles – Many beams from many directions!

Carefully evaluate plans

Develop dose constraints – understand normal tissue tolerance

Follow nationally accepted guidelines e.g., RTOG compactness criteria (PTV + 2 cm)

Compactness Constraints

5) Intermediate Dose Spillage

The fall-off gradient beyond the PTV extending into normal tissue structures must be rapid at all directions and meet the following criteria:

a) Depth

The maximum total dose over all 3 fractions in Gray (Gy) to any point 2 cm or greater away from the PTV in any direction must be no greater than D_{95}\% where D_{95}\% is given by the table below.

b) Volume

The ratio of the volume of the 30 Gy isodose volume to the volume of the PTV must be no greater than R_{30}\%, where R_{30}\% is given by the table below. This table is used for all prescription requirements in Section 6.4.2 irrespective of calculation algorithm and dose treatment volume.

<table>
<thead>
<tr>
<th>Maximum PTV Dimension (cm)</th>
<th>Ratio of isodose volume to the PTV, D_{95}%</th>
<th>Ratio of 30 Gy isodose volume to the PTV, R_{30}%</th>
<th>Maximum Dose, cGy from PTV</th>
<th>Percent of Lung receiving 20 Gy total or more, V_{20Gy} (%)</th>
<th>PTV volume (Gy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>none</td>
<td>none</td>
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<td>none</td>
<td>none</td>
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<tr>
<td>2.0</td>
<td>&lt;1.5</td>
<td>&lt;1.8</td>
<td>&lt;2.5</td>
<td>&lt;10</td>
<td>10</td>
</tr>
<tr>
<td>2.5</td>
<td>&lt;1.2</td>
<td>&lt;1.4</td>
<td>&lt;1.3</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>3.0</td>
<td>&lt;1.1</td>
<td>&lt;1.1</td>
<td>&lt;1.1</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>3.5</td>
<td>&lt;1.0</td>
<td>&lt;1.0</td>
<td>&lt;1.0</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>4.0</td>
<td>&lt;0.9</td>
<td>&lt;0.9</td>
<td>&lt;0.9</td>
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<td>10</td>
</tr>
<tr>
<td>4.5</td>
<td>&lt;0.8</td>
<td>&lt;0.8</td>
<td>&lt;0.8</td>
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<td>10</td>
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<td>5.0</td>
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<td>&lt;0.7</td>
<td>&lt;0.7</td>
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<td>&lt;0.6</td>
<td>&lt;0.6</td>
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<td>10</td>
</tr>
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<td>6.0</td>
<td>&lt;0.5</td>
<td>&lt;0.5</td>
<td>&lt;0.5</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>6.5</td>
<td>&lt;0.4</td>
<td>&lt;0.4</td>
<td>&lt;0.4</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>7.0</td>
<td>&lt;0.3</td>
<td>&lt;0.3</td>
<td>&lt;0.3</td>
<td>10</td>
<td>10</td>
</tr>
</tbody>
</table>

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**Errors in SRS / SBRT**

**What Happened?**

"Basically, they were supposed to have a second physicist independently verify the calibrations of the first physicist," said Bill Passetti, the bureau's chief. "It looks like the second verification wasn't performed, which is a violation of the facility's protocol and procedures."

**Who caught it, and what could have been done to prevent it?**

RPC caught it, but not until after 77 patients had been treated

Don't rely on Excel – perform hand calc

Perform independent checks

Use mailed dosimetry service as part of commissioning, before patients are treated

---

**Patients exposed to high radiation levels**

[Dosimetric stereotactic radiosurgical accident: Study of 33 patients treated for brain metastases.]

*Neurothrive*. 96(3): 662-75, 2010


33 patients with 57 brain mets
Mean volume: 3.2 cc [0.04 – 14.07]
Mean prescribed dose: 20 Gy [10 – 23]
Mean delivered dose: 31.5 Gy [13 – 52]
Mean overdose: 61.2% [5.6 – 226.8]
Local control: 80.7%
No morbidity observed

32 unilateral ACN patients
31% 12 month actuarial rate of trigeminal neuropathy
Who caught it, and what could have been done to prevent it?

Vendor caught it, but not until after 145 patients had been treated

Better training on small field dosimetric methods

Compare beam data with colleagues

Perform comprehensive commissioning including dosimetric verification of TP calculations

Who caught it, and what could have been done to prevent it?

New physicist caught it, after attending vendor training, but not until after 152 patients had been treated

Better training on small field dosimetric methods

Compare beam data with colleagues

Perform comprehensive commissioning including dosimetric verification of TP calculations

SRS treatment for a benign tumor

Overdoses ranging from 25 to 100%

Patient developed facial spasms, balance and memory problems

Figure 6. Scatter factors measured in 6 MV photon beams with a 0.65 cm$^2$ Farmer chamber (triangles) and a 0.01 cm$^3$ Pinpoint chamber (circles) (A. Lisbona, personal communication)
Accurate measurement of small field output factors has challenged many physicists

Unnamed U.S. Institution, July, 2010

<table>
<thead>
<tr>
<th>Cone size (mm)</th>
<th>Original Output Factor</th>
<th>Re-measured Output Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.0</td>
<td>0.312</td>
<td>0.699</td>
</tr>
<tr>
<td>7.5</td>
<td>0.610</td>
<td>0.797</td>
</tr>
<tr>
<td>10.0</td>
<td>0.741</td>
<td>0.835</td>
</tr>
<tr>
<td>12.5</td>
<td>0.823</td>
<td>0.871</td>
</tr>
<tr>
<td>15.0</td>
<td>0.862</td>
<td>0.890</td>
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<td>17.5</td>
<td>0.888</td>
<td>0.904</td>
</tr>
<tr>
<td>20.0</td>
<td>0.903</td>
<td>0.913</td>
</tr>
<tr>
<td>25.0</td>
<td>0.920</td>
<td>0.930</td>
</tr>
<tr>
<td>30.0</td>
<td>0.928</td>
<td>0.940</td>
</tr>
</tbody>
</table>

There was ample opportunity to avoid these errors

LESIONS FROM RECENT ACCIDENTS IN RADIATION THERAPY IN FRANCE

Institut de Radiologie et de Sûreté Nucléaire, Direction de la Radiothérapie de l'Hôpital BRSN,
BP 17, F-14776 Vincennes cedex, France

Accurate measurement of small field output factors has challenged many physicists. There was ample opportunity to avoid these errors.

Single fraction SRS for AVM, November, 2004

Prescription dose not reported; plan/treatment used multiple isocenters, with collimators from 10 - 30 mm

Jaws set to 40 x 40 cm² instead of 40 x 40 mm². Physicist told therapist “40 x 40”

Some areas of normal brain received in more than dose to intended target

Severe complications: “fibrosis and osteotracheal fistula that required surgical operation.” Patient died several days later as a result of a “brutal haemorrhage.”

Errors in SRS / SBRT

Then, in what seemed like a blink of an eye, she disintegrated. “Four weeks later, she was like a vegetable,” Mr. Kagan said. “It was mind-boggling to see one person who was not elderly deteriorate that quickly.” Now, she can only blink her eyes and tightly squeeze her husband’s hand. “It is very hard on the kids,” Mr. Faber said. “It has been hard on me but really nothing compared to what Marci is going through.” Doctors who deal with her type of radiation injury say the prognosis for any meaningful recovery is poor.
Who caught it, and what could have been done to prevent it?

Patients / staff “caught” it

Better communication

Use of checklists

Machine Interlocks

Perform comprehensive, end-to-end commissioning of overall process, including R/V system

UCLA Radiation Oncology - Radiosurgery Check List

<table>
<thead>
<tr>
<th>Step</th>
<th>Encounter 1</th>
<th>Encounter 2</th>
<th>Encounter 3</th>
<th>Encounter 4</th>
<th>Encounter 5</th>
<th>Encounter 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Arrange sheet and pad on couch.</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>2</td>
<td>Set the couch to 0 &amp; coll to 90.</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>3</td>
<td>Take photos of patient (3).</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>4a</td>
<td>Set backup jaws to 4.0 x 4.0 cm. (2 initials &amp; size).</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>4b</td>
<td>Install the cone. (2 initials &amp; size).</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>5</td>
<td>Position isocenter templates on positioning box. 2 init.</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>6</td>
<td>Enable linac switches 1, 2, and 4. Unlock microadjusters/table locks.</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>7</td>
<td>Fit ring onto patient head frame.</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>8</td>
<td>Attach large bolts (2 per ring).</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>9</td>
<td>Secure frame to couch mounts. Tighten large bolts.</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>10</td>
<td>Secure patient to couch w/ strap.</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>11</td>
<td>Attach positioning box to the frame.</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>12</td>
<td>Position positioning box to the isocenter.</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>13</td>
<td>Tighten Lat &amp; Long axis locks and biplane jaws switches 1, 2, 4.</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>14</td>
<td>Use microadjusters, reposition box to isocenter, lock microadjusters.</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>15</td>
<td>Review of fields by physician.</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
</tbody>
</table>

Vendor Response

One vendor’s solution

Figure 2: Recommended rear decal location for Varian coneir colimator

<table>
<thead>
<tr>
<th>RCV/R Radio</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1000064810</td>
<td>Label framing (High)</td>
</tr>
<tr>
<td>1000064810</td>
<td>Label framing (Cheek)</td>
</tr>
<tr>
<td>1000064810</td>
<td>Label framing (Medial)</td>
</tr>
<tr>
<td>1000064810</td>
<td>Label framing (Lateral)</td>
</tr>
<tr>
<td>1000064810</td>
<td>Label framing (Labiial)</td>
</tr>
<tr>
<td>1000064810</td>
<td>Label framing (Nasal)</td>
</tr>
<tr>
<td>1000064810</td>
<td>Label framing (Germinal)</td>
</tr>
</tbody>
</table>
Do all of your commissioning in clinical mode, and through your Verify/Record system.

A verify/record system can help to minimize errors....

....as long as it is configured properly.

End-to-end, image guided dosimetric assessment

End-to-end, image guided dosimetric assessment
SRS/SBRT programs should be subject to independent review

Lung SBRT Credentialing

Wrong site errors in SRS/SBRT

<table>
<thead>
<tr>
<th>Event Description</th>
<th>Treatment Implication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient orientation entered incorrectly at MRI scanner</td>
<td>Wrong location treated</td>
</tr>
<tr>
<td>Cardiac box not seated properly during CT imaging</td>
<td>Wrong location treated</td>
</tr>
<tr>
<td>Malfunction of automatic positioning mechanism following re-initialization</td>
<td>Wrong location treated</td>
</tr>
<tr>
<td>Right homologous nerve targeted instead of left</td>
<td>Wrong location treated</td>
</tr>
<tr>
<td>Right homologous nerve targeted instead of suspected nerve</td>
<td>Wrong location treated</td>
</tr>
<tr>
<td>Mistake in setting isocenter coordinates</td>
<td>Wrong location treated</td>
</tr>
<tr>
<td>Patient not secured to stereotactic device or platform</td>
<td>Wrong location treated</td>
</tr>
<tr>
<td>Selected collimators did not match planned</td>
<td>Wrong dose/distribution delivered</td>
</tr>
<tr>
<td>Physician mistakenly typed 28 Gy instead of 18 Gy into planning system</td>
<td>Wrong dose delivered</td>
</tr>
<tr>
<td>Physician calculated prescription to 50% isodose instead of 40%</td>
<td>Wrong dose delivered</td>
</tr>
<tr>
<td>Microphone dislodged, causing stereotactic device to break</td>
<td>Treatment halted after 2 of 5 fractions</td>
</tr>
<tr>
<td>Mouth relaxed during treatment</td>
<td>None, personnel interrupted treatment</td>
</tr>
</tbody>
</table>
A written checklist system can help minimize errors

### Trigeminal Neuralgia Treatment Time Out

This form is to be signed at the treatment console. Physician, Physicist, ExacTrac Therapist and Treatment Therapist all present. Treatment cannot be initiated until all parties agree on treatment and sign this form.

<table>
<thead>
<tr>
<th>Affix</th>
<th>Patient</th>
<th>Label</th>
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**Circle One**

- Treatment side verbally confirmed with patient
- Treatment side visually confirmed by physicist (Behaviors)
- Treatment side confirmed with patient record

**Other Sources of Information**

- **MAUDE** is voluntary

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### Other Errors

- **Circular collimator left off**

### Other Sources of Information

- **ELECTOR INSTRUMENTS INC.**
  - **LEXELL CLINICAL KNEE RADIATION THERAPY**
  - **Update Search Results**

  **Event Type**: Injury
  **Event Description**: Lekelx Clinical Nemeology system was installed in 2002 (5/2). From the beginning, the accuracy was not correct according to the D5/4 target coordinates. The Lekelx clinical module was used to scan the patient's head and then used for planning. The accuracy was confirmed by spot images, but the treatment was not possible due to the incorrect settings.
Efforts to Improve Safety

Many European countries have legislatively-mandated reporting of radiation incidents.

Funded by ESTRO, began in 2001
Voluntary, anonymous, web-based reporting system
~20 countries participating, ~700 incidents reported

Efforts to Improve Safety

Must provide dose form every CT scan by 2012 (and must be accurate within 20%, verified annually by a medical physicist)

Must credential all CT facilities by 2013

New reporting requirements for radiotherapy misadministrations


Recent U.S. Efforts
Recent U.S. Efforts

Series of 5 safety white papers

- IMRT
- IGRT
- SRS/SBRT
- HDR
- Peer Review

Written by 8 “experts”
Reviewed by 8 independent “experts”
Endorsed by AAPM, ACR, AAMD, ASRT
Reviewed by AANS, MITA, public

Recent U.S. Efforts

SRS/SBRT White Paper

SRS/SBRT as a well thought out program, not an addition/afterthought
Team approach, plan ahead
SRS/SBRT specific training
SRS/SBRT expertise/competence, including personnel certification
Follow nationally accepted standards, clinical and physics
SRS/SBRT accreditation / credentialing
Adequate resources:
  - Time, equipment, personnel
  - Quality management system, including reporting and ongoing quality improvement, and peer review
  - Physician and physicist supervision for each procedure

Practice Accreditation Programs – should be MANDATORY

And, specific accreditation programs for specialized programs such as SBRT should be developed, and required

Board certification is a minimum requirement for physicists

“Finally, it may be time to acknowledge that some radiotherapy procedures, including perhaps SRS and SBRT, share more in common with other specialized medical procedures (e.g., heart or liver transplants), and should perhaps be performed only by highly experienced personnel at recognized centers of excellence.”
Vendor Responsibility

There must be dialogue and communication between equipment manufacturers and end-users on the approaches, system design, QA methodology, and clinical implementation of SRS and SBRT. The vendors need to understand the needs and requirements of the clinicians, medical physicists, radiotherapists relative to the systems and processes of SRS and SBRT. With such understanding they must exert all the necessary efforts to incorporate features and safeguards to assure efficacious and safe operation of their products. By the same token, the end-users need to work with the manufacturers in developing commissioning, safety and quality assurance tools, programs and procedures for SRS and SBRT systems.

Vendor Responsibility

Vendors must provide additional opportunities for specialized training, emphasizing implementation, clinical and quality assurance in addition to technical aspects, and the home institution must make available resources and time for such training. It is not adequate to train users on the basic aspects of system operation if the systems are sold and used for specialized purposes such as SRS and SBRT.

Vendors must do more to emphasize all QA aspects, not only equipment QA, but process QA. SRS / SBRT systems consist of multiple components, and vendors must ensure and demonstrate full mechanical, electronic and information connectivity of these components. In situations where components or subsystems come from more than one manufacturer, it is the responsibilities of the manufacturers to collaboratively demonstrate compatibility of the various subsystems, and their safe operation when used in combination.

Vendor Responsibility

Finally, while a turn-key approach to the use of complex clinical systems is appealing in terms of procedural simplicity, inadequate understanding of the internal workings of such complex systems by the end-users is of concern. Rather, vendors should take an "all-inclusive" approach of safe equipment design, understanding the need for QA equipment and procedures, and emphasizing commissioning, safety and quality assurance requirements and procedures.

SAbR will completely change the practice of radiation oncology and management of cancer

Doing so requires a systematic approach to clinical practice and technology

complete diligence on the part of both physicians and physicists

and adherence of a culture of safety on the part of all stakeholders

Thank you