Accidents in radiation therapy in France: causes, consequences and lessons learned
MEDICAL LINEAR ACCELERATORS

- Photon beam (MV)
- Electron beam (MeV)
**PRECISION REQUIRED IN RADIOTHERAPY**

Precision required by radiation therapists:

\[ 2\sigma = 5\% \text{ (ICRU 24, 1976)} \]

<table>
<thead>
<tr>
<th>Present technique</th>
<th>Future development</th>
</tr>
</thead>
<tbody>
<tr>
<td>(100 \times \Delta D(1\sigma)/D)</td>
<td>(100 \times \Delta D(1\sigma)/D)</td>
</tr>
<tr>
<td>Absorbed dose determination at the calibration point</td>
<td>2.0</td>
</tr>
<tr>
<td>Additional uncertainty for other points</td>
<td>1.1</td>
</tr>
<tr>
<td>Monitor stability</td>
<td>1.0</td>
</tr>
<tr>
<td>Beam flatness</td>
<td>1.5</td>
</tr>
<tr>
<td>Patient data uncertainties</td>
<td>1.5</td>
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<tr>
<td>Beam and patient set-up</td>
<td>2.5</td>
</tr>
<tr>
<td>Overall excluding dose calculation</td>
<td>4.1</td>
</tr>
<tr>
<td>Dose calculation</td>
<td>1.0 2.0 3.0 4.0 5.0</td>
</tr>
<tr>
<td>Resulting overall uncertainty</td>
<td>4.2 4.6 5.1 5.7 6.5</td>
</tr>
</tbody>
</table>

Precision goal for physicists (1\(\sigma\))

(Ahnesjö and Aspradakis, 1999)
WHAT IS AN ACCIDENT IN RADIOTHERAPY?

- ICRP 86 (2000):
  - Accidental exposure = any substantial discrepancy between prescription and delivery (identification of the patient, definition of target volume, fractionation, dose distribution…)

- FDA class I risks (AAPM TG35, 1993):
  - Type A: overdose $\geq 25\%$ : can directly cause complications threatening the patient’s life
  - Type B: overdose $\geq 5$ and $< 25\%$ or under-dose: increases the probability of an unacceptable consequence of the treatment (higher risk of complications or reduced tumor control)
ACCIDENTS DECLARED IN FRANCE SINCE 2005

<table>
<thead>
<tr>
<th>Where</th>
<th>When</th>
<th>Patients involved</th>
<th>ASN/SFRO score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case 1</td>
<td>2003</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Case 2</td>
<td>2004</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Case 3</td>
<td>2004</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Case 4.1</td>
<td>May 2004 - May 2005</td>
<td>24</td>
<td>6</td>
</tr>
<tr>
<td>Case 4.2</td>
<td>2001-2006</td>
<td>397</td>
<td>3</td>
</tr>
<tr>
<td>Case 4.3</td>
<td>1987-2000</td>
<td>312</td>
<td>n.d.*</td>
</tr>
<tr>
<td>Case 5</td>
<td>April 2006 - April 2007</td>
<td>145</td>
<td>n.d.*</td>
</tr>
</tbody>
</table>

* Not determined

Why?

Because declaration to the national authorities is mandatory since 2001…
CASE 1

- Treatment of head and neck cancer:
  
  New linac with internal motorized wedge
  RX 6 MV
  Fields: wedged
  5 cm x 5 cm + 4 cm x 4 cm boost

- 4 cm x 4 cm boost with wedge:

  ![Diagram showing treatment setup]

  - TPS
  - Record & Verify
  - Linac control

  - In-house MU calculation software
    Never used for internal wedge
  - Nb of total MU: ok
  - Nb of filtered MU = 0
  - All MU without wedge
CASE 1

● Consequences :
  - Overdose at prescription point > 20%
  - Complications : necrosis ⇒ total laryngectomy

● Lessons learned :
  - Potential errors :
    • In-house software : not tested, not qualified
    • Connection between softwares : not tested, not qualified
  - Prevention:
    • QA for softwares and connections (computer network)
    • *In vivo* dosimetry
CASE 2

- Treatment of intracranial AVM

Linac + additionnal cylindrical collimator
RX 6 MV
Fields:

  - linac collimator: 40 mm x 40 mm
  - additionnal collimator: Ø = 10 → 30 mm

- First part of the treatment:

  « Collimator aperture = 40 x 40 »

linac collimator: 40 cm x 40 cm
CASE 2

- Consequences:
  - High dose outside target volume
  - Overdose undervalued by local team
  - Complications: fibrosis + oeso-tracheal fistula → surgical operation → death from brutal haemorrhage

- Lessons learned:
  - Potential errors:
    - Additional accelerator accessory without safety device
    - Overdose evaluation by local team
  - Prevention:
    - Safety of treatment machine (entire system)
Treatment of prostate cancer:
RX 25 MV
Fields : 5 MLC fields (4 wedged)
Implementation of « dynamic wedge »

Wedge factor (WF) = \( \frac{\text{dose with wedge}}{\text{dose without wedge}} \)

MU calculation with physical wedge but treatment with dynamic wedge:

\[
\frac{\text{WF}_{\text{dynamic}}}{\text{WF}_{\text{physical}}} = 1.3 \ (30^\circ) \rightarrow 1.5 \ (45^\circ)
\Rightarrow \text{overdose} = 20\% \rightarrow 35\%
\]
**CASE 4.3**

- All isocentric treatments

- Reference conditions for measurement of dose rate (cGy/MU):
  
  - Overdose:
    - SAD = 100 cm
    - $d_{max} = 1.5$ cm for 6 MV
    - 2.7 cm for 12 MV
    - 3.5 cm for 25 MV

- MU calculation using reference dose rate, without correction for distance:
  
  \[
  \text{Nb of MU (isocentric)} = \frac{D}{D_r \times \frac{100 + d_{max}}{100} \times OF \times TMR \times F_w \times F_{trans}}
  \]
CASES 4.1 and 4.3

● Consequences:
  – Case 4.1: 1+4 deaths and 10 severe/disabling complications (rectitis, cystitis, fistula)
  – Case 4.3: Follow up of the « 25 MV cohort » at risk (n=120)

● Lessons learned:
  – Potential errors :
    • Wrong use of TPS due to lack of training + unsafe screen display
    • Calculation error due to in-house software, not tested, not qualified
  – Prevention :
    • Time and organisation for continuous training
    • Softwares with safe human-computer interaction
    • *In vivo* dosimetry and second independent calculation
CASE 5

- Stereotactic radiosurgery with micro MLC:
- Calibration measurements (scatter factors) made with wrong detector:

Sensitive volume of « Farmer » ionisation chamber

« Farmer » chamber : 0.65 cm³
« Pinpoint » chamber : ≤ 0.03 cm³
CASE 5

● Consequences:
  – Overdose: up to ~200%

● Lessons learned:
  – Potential errors:
    • Usual dosimetric material not adapted to special techniques
    • Errors due to lack of expertise (special techniques)
  – Prevention:
    • Special techniques only accessible to expert teams
    • Verification of the dose delivered in treatment conditions
    • External audit also for special techniques
LESSONS LEARNED FROM ACCIDENTS

- Knowledge of potential errors on dose determination or delivery
- Prevention: QA and safety culture
FRANCE: LESSONS LEARNED

- Publications on lessons learned from accidents in RT need to be updated:
  - Risks of new technologies and special techniques
  - Criteria to define and classify accidental exposures

- ASN/SFRO gravity scale (2007):
  - After Common Terminology Criteria for Adverse Events (CTCAE V3.0)
  - Incidents (scale 1 to 3) and accidents (4 to 5)

- *In vivo* dosimetry and MU calculation with independent software are now mandatory in France

- External audits need to be done for all clinically relevant irradiating conditions

- Need to develop research on overdose complications
FRANCE: NATIONAL REFORM OF RADIOTHERAPY

- Quality assurance (ISO 9000; agreement criteria; protocols)
- National reporting system (guide; scale; feed-back)
- Human resources (increase; continuous training)
- Safety of installations and softwares (quality and safety standards, internal and external quality controls, human-machine interaction)
- Information of the patients, the doctors and the public
- Inspections
- National overview and follow-up
IRSN

- Research and expertise for the management of accidents: retrospective dosimetry, radiopathology (diagnosis, prognosis, treatment)

- Study on the improvement of the security of RT treatments thanks to the development of a safety culture (IRSN Report n°2008-2):
  - Immersion of IRSN experts in nuclear safety (human and organizational factors, software safety) in radiotherapy departments
  - How to apply and adapt concepts and methods of nuclear safety culture in the field of radiation therapy

- Set up of a continuous training program on risk management for RT professionals (radiotherapists, medical physicists, radiologists...):
  - Theoretical approach (defense in depth, risk management)
  - Application in the radiotherapy department
INTERNATIONAL

- ICRP: a WG is updating the report on accidents in radiation therapy

- European project ROSIS (ESTRO): international web system for anonymous and voluntary reporting of incidents in radiotherapy

- International conference “Modern radiotherapy: challenges and advances in radiation protection of patients” (Paris, 2-4 December 2009)