Lessons learned from accidents in Brachytherapy

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Brachytherapy History

- Radium discovered by Pierre and Marie Curie was the initial isotope used.
- In use since early 1900.
- Term defined by Forsell in 1931.
- It is also called Curietherapy.
- Accidents and events reported early and continue.
Brachytherapy History: Early Event Report

- Radium tubes sterilized in unattended boiling water that evaporated: tube broke. Radon and Radium salt contamination of floor and walls.
- Multiple persons circulated: party!!
- Contamination was transported in shoe soles to homes.

Christie Hospital
Brachytherapy History

• Hot Sources: temporal or permanent.
• Manual hot source after loading
• Remote after loading.
Brachytherapy History

Hot Sources

- **Tubes**: cervix, uterus, vagina, nasopharynx.
- **Needles**: soft tissues, tongue, neck, parametrium.
- **Wires**: breast, soft tissue, parametrium.
- **Seeds**: prostate, bladder, brain.
Hot Sources Problems

- Irradiation to staff.
- No correction of implants.
- Great experience needed.
- Migration of source.
- Discharge of patients.
Hot Sources Seeds

- Prostate, soft tissues $^{125}_{1}I$, $^{103}_{1}Pd$
- More than 50,000 per year.
- No accidents reported.
- Doses to comforters and carers. below 1 m Sv/year.
- Precautions to pregnant partners.
Hot Sources Seeds Problems

- Migration: urine, semen, lungs, gastrointestinal.
- Cremation: activity in ashes and airborne (inhalation by cremation staff).
  - Time delay recommendation from 3 (Pd) to 12 (I) months.
  - Remove Prostate.
- Post implant surgery (surgeons).
- Fertility.
Fertility

Usually infertile

Fathering possible: limited risk of genetic effects for the child.
Under Reporting

• More frequent in small centers.
• Mutual trust between regulators and users.
• Operator must take responsibility for safety.
• Reports to improve safety not punishment.
• Punish those who try to hide problems.
Safety

• Every body is responsible.
• Training essential.
• Administrators responsibility for training.
• Ensure quality system.
Example of serious event

A. Sequence of Events.

- February 2002, PVAMC initiated its prostate brachytherapy program and implanted its first patient.
- February 2003, during a seed prostate implant, many seeds (40 out of 74) were mistakenly implanted into the patient’s bladder and subsequently recovered.
B. **Sequence of Events.**

- October 2005, during a seed prostate implant, many seeds (45 out of 90) were again mistakenly implanted into the patient’s bladder and subsequently recovered.
- May 2008, the NHPP notified the NRC of a possible medical event involving a patient that received a dose to the prostate that was less than 80 percent of the prescribed dose.
C. **Sequence of Events.**

- July 2008, the PVAMC appointed an Administrative Board of Investigation.

D. **As of October 2008, 92 medical events identified and reported.**

E. **Total Medical Events.**

- 57 Medical Events due to a dose less than 80% of the prescribed dose.
- 35 dose to other organ (rectum, bladder).
F. Causes of Medical Events.

1. Incorrect Placement of Seeds.
2. Inadequate Procedures.
3. Poor Management Oversight of Contractors.
4. Inadequate Training of Licensee staff.
5. No peer review.

G. Corrective Actions Taken.

1. Suspended the prostate brachytherapy program on June 11 2008, and ordered an external review of the prostate brachytherapy program by an Administrative Board of Investigation.
Adherence to QA programme

- It must be strict.
- Failure of professionals to adhere can lead to unacceptable rates of adverse events.
- Professionals and administrative staff must adhere.
Brachytherapy
Afterloading

• Manual.

• Automated.
Manual Hot Source After Loading

- Great part of brachytherapy in developing countries: cervix and vagina most common.
- Needles, applicators or tubes inserted in tissues or cavities.
- Radioactive material inserted after dosimetry to applicators, needles or tubes.
- Sievert in 1937 started remote manual after loading.
Manual Hot Source After Loading

Events

• Sources lost.
• Wrong patient.
• Calculation errors.
• No deaths reported.
Automated Remote After Loading

- 1980.
- High activity sources.
- Dwell times short.
- Accuracy to a fraction of a second.
- Single to few fractions required.
- MDR, HDR, PDR.

MDR 2-12 Gy/h, HDR +12 Gy/h
Risks

• Full chain procedures.
• Transport of over 10,000 sources/year.
• More than 1,000 centers.
• Source replacement 3 to 4 per year.
• Different levels of training.
• More than 500,000 procedures.
• More than 500 accidents reported.
Lessons Learned
Events have different origins

• The handling and transport of the sources;
• Inadequate shielding:
• Sources in transit (sources remaining in the safe, in the patient, or along the transfer tubes).
• Treatments given to wrong patients, wrong sites; and
• Incorrectly prescribed doses, or repeated treatments to the same patient.
Packing and transport

- More than 10,000 shipments occur yearly.
- Sources are transported twice (delivery and returned).
- Sources should be installed and secured properly in the shielded position.
- Events have lead to exposure to drivers, handling operator, administrators and public.
- Cobalt microsources reduces shipments.
Packing and transport

Cases Reported

• Accidental damage containers.
• Intentional actions ⇒ heft of vehicle.
Packing and transport

• Source outside transport safe and not secured. Detected: Source moved to shielded position.
• Returned source: high dose detected: 32 persons had been exposed. An alliance driver 5.82 mSv, an American Crating employee 46.13 mSv in several hours, Federal driver 0.84 mSv.
• Overpack damage after falling from conveyor. A new overpack was sent and shipment continued.
Exposures to personnel and the Public

- Source exchange
- Public in waiting area because of flaws in the bunker design.
Faulty Connection

• Transferring a source: Inadvertently connected transfer wire backwards. Engineer briefly (0.25 s) touched the guide to return the source.
• He received 1 mSv whole body, 21 mSv left thumb and index finger.
• Cause: Not following established order of procedures.
Bunker

• A dose of 470 μSv/h detected in public waiting area on top of bunker instead of < 20 μSv/h.
• Shielding was then added and dose come to under 20 μSv/h
Events during operation

Greatest cause of misadministration and accidents

- Mechanical problems.
- Human errors.
Mechanical and Computer Events

- HDR control unit.
- Computer.
- Source cable.
- Catheter.
- Applicators.
Examples reported of Mechanical and Computer events

- Loss of power to the control unit stopped its operations, which necessitated manual means to interrupt the treatment.
- During treatment, the stop button in the console did not retract the wire source.
- Power failure with subsequent failure of the computerized security program, which allowed incorrect calculation after wrong data entry.
- The source cable either became disconnected or kinked or the interlock failed and the source stayed in the exposure position with resultant clinical consequences. Also, premature and abrupt termination of treatment has been reported.
- Displaced/dislodged applicators have resulted in thigh irradiation when vaginal treatment was intended; during treatment of lung cancer, another unrelated lung area was treated.
- Blood contaminating the source tube and the source during use of open-ended catheters. The use of these catheters is at variance with the recommendation that only closed systems should be used.
Treatment planning software error or human error

• The treatment planning software error created an unexpected step size and dose was delivered outside the treatment area. The event was a consequence of treatment plan entered manually after the system rejected the electronic transfer and it changed the step size from 2.5 to 10 mm.
Reported Human Errors

- Incorrect medical indication.
- Patient identification.
- Diagnosis.
- Area of treatment.
- Prescription.
- Data entry.
- Catheter.
- Applicator.
Human errors

1. Wrong patient. Identification problem lead to treatment in other site (lip instead of nose)
2. Reverse order of entry of dwell positions. Resulted in 8 Gy instead of prescribed 5 Gy.
3. Inadequate default position for start of dwell sites. The treatment started 6 cm. beyond the intended location (gastric irradiation, esophagus cancer)
4. Kink in catheter. Source lodged in the catheter and resulted in radiation of the trachea instead of the bronchi.
5. Dwell position error. A double step length was entered in a vaginal irradiation resulting in irradiation of the vulva.
Wrong catheter

- Patient had a catheter in the urethra and another in the bladder. The source was introduced to the bladder.

- Catheter Wrong length
  Catheter planned to treat bronchus was 150 cms. long. A 125 cms. was used and cheek and eye were irradiated.
Recomendations

• Keep external tubes for from patient.

• Homemade test wire recommended for manual insertion with a mark.
Human Error

Wrong orifice

- The applicator was inserted in the rectum instead of the vagina.
Human and Organization Error

- Double dose administration: change of personnel; the second shift repeated treatment.
• Most cases reported were part of fractionated treatment which can be compensated except in the last fraction.
Only one case of death is reported

• Anorectal cancer + XRT programmed for perineal interstitial brachytherapy.
• Brachy aborted because of source transfer problems.
• Returned to nursing home.
• Patient deteriorated
• Flexible tube fell from the patient day 4 and placed in waste.
• Patient died day 5.
Reasons

• Failure of weld between the transfer wire and source: first event.
• Machine showed failure of source return.
• Room monitors showed residual radiation after treatment.
• Staff ignored machine and room monitors.
• No monitoring of patient after procedure.
Why?
Accumulation of errors

• Equipment failure.
• Human failure.
• Organizational error.
Main Points: Permanent Implants

Summary

• The use of permanent radioactive implants to treat selected localized prostate cancers is increasing rapidly all over the world.
• No adverse effects to medical staff and/or the patient’s family have been reported to date.
• The annual dose from patients to family or household members remains well below 1 mSv in almost all cases.
• Expulsion of sources through urine, semen, or the gastro-intestinal tract is a rare event. Simple recommendations should allow the patient to minimize all radiation risks in case of such an expulsion.
• Cremation can be allowed if 12 months have elapsed since the implantation. If cremation is to be considered before that time, specific measures must be undertaken.
• The patient must be provided with specific recommendations concerning the previous points, subsequent pelvic or abdominal surgery, fathering of children, and possible triggering of some security monitors.
Maint Points: HDR Summary 1

• High-dose-rate (HDR) brachytherapy is a rapidly growing technique that has been replacing low-dose-rate (LDR) procedures over the last few years in both industrialized and developing countries. It is estimated that about 500,000 procedures (administrations of treatment) are performed by HDR units annually.

• LDR equipment has been discontinued by many manufacturers over the last few years, leaving HDR brachytherapy as the major alternative.

• HDR techniques deliver a very high dose, of the order of 1.6-5.0 Gy/min, so mistakes can lead to under- or over dosage with the potential for clinical adverse effects.

• More than 500 HDR accidents (including one death) have been reported along the entire chain of procedures from source packing to delivery of dose. Human error has been the prime cause of radiation events.

• Many accidents could have been prevented if staff had functional monitoring equipment and paid attention to the results.
Maint Points: HDR Summary 2

• Since iridium has a relatively short half-life, the HDR sources need to be replaced approximately every 4 months. Over 10,000 HDR sources are transported annually, with the resultant potential for accidents.

• A team of trained personnel following quality assurance (QA) procedures is necessary to prevent accidents. QA should include peer review of cases.

• Accidents and incidents should be reported and the lessons learned should be shared with other users to prevent similar mistakes.

• Cobalt miniature source HDR equipments will contribute to reduce source transportation.
Recomendations

• A written comprehensive QA program is essential.
• Compliance with QA procedures will contribute to minimize the occurrence of errors, both in number and magnitude.
• While not necessarily required by regulation, a hospital radiation safety committee (QA committee) needs to exist and interact with regulatory and health authorities.
• Maintenance is an indispensable component of QA.
• External audits of procedures re-enforces good and safe practice, and identifies potential causes of errors.
• All significant steps from prescription to final delivery of treatment should be checked and verified by a second competent person. The objective is to ensure that the correct patient receives the correct dose at the correct site.
• Peer review of each case improves quality.
• Every incident or accident should be reported as required to the appropriate authority.