Errors in Radiation Therapy

ABSTRACT

Radiation therapy is a highly regulated medical practice with historically low error and injury rates. Rare instances of radiation therapy errors resulting in severe injuries have been documented. These errors can result in devastating and sometimes fatal injuries, especially when the misadministration results in injury to vital organs or structures, such as the spinal cord, heart, lungs, or brain. Delivering radiation therapy is a team effort requiring collaboration and clear communication between the radiation oncologist, medical physicist, dosimetrist, and radiation therapist/technologist. As technology advances and computers are routinely used to plan, verify, and deliver radiation therapy, an information technologist may also be included on the team. Preventing errors in the delivery of radiation therapy involves not only understanding and appropriately utilizing new advances in technology, but also utilizing established patient safety procedures that optimize safe healthcare delivery. (Pa Patient Saf Advis 2009 Sep;6[3]:87-92.)

Introduction

Radiation therapy is used in the treatment of approximately 40% to 60% of patients who are diagnosed as having cancer.[1,2] Radiation therapy uses ionizing radiation delivered by external beam therapy or radioisotopes with either a palliative or curative goal.[1] These complex treatments are usually delivered daily during a period of five to seven weeks.[1,2] Radiation therapy is recognized as a high-risk procedure because of the number of steps and staff involved.[3] The radiation oncologist, medical physicist, dosimetrist, and radiation therapy technician work in concert to prescribe, plan, and deliver radiation therapy. The goal is to deliver a prescribed dose of radiation to the patient's tumor site, while restricting the dose to all surrounding healthy tissue and organs to that less than or equal to normal tissue tolerance.[4]

While errors in the delivery of radiation therapy are rare and usually result in little or no injury to a patient, the real danger is if an error in administration goes undetected.[5] This may result in healthy tissue being exposed to unnecessary levels of radiation or the tumor site not receiving a full effect of therapy. When radiation misadministrations are caught early, subsequent treatment doses can be adjusted so that the patient avoids receiving an under- or overdose. A severe misadministration may result in radiation necrosis to vital organs/structures and can be fatal. A highly publicized case of radiation misadministration resulting in a fatality occurred in Glasgow, Scotland, in 2005, in which a young patient, Lisa Norris, received a 58% higher dose than ordered to her craniospinal area. An autopsy revealed that her tumor was still present despite radiation therapy.[6] Another example of radiation misadministration involved the Therac-25 incidents, which occurred between 1985 and 1987. Two different computer software errors in a computerized linear accelerator resulted in massive radiation overdoses that injured six patients and caused two fatalities.[7]

Due to the low incidence of radiation therapy errors, many radiation therapy professionals may never encounter a significant misadministration during their career. This article focuses on types of external beam radiation therapy events reported in Pennsylvania and in the literature related to external beam radiation therapy. The most common errors reported include patients receiving the wrong dose of radiation, the wrong site being treated, and the wrong patient being treated. In a review of three decades of documented radiation therapy patient safety incidents, adverse events, near misses, and errors sponsored by the World Health Organization's World Alliance for Patient Safety, causal factors implicated in these adverse events were found to be errors in therapy planning, treatment delivery, and information transfer, as well as lack of knowledge and experience in using radiation therapy equipment and/or computer software.[8] Additionally, this article reviews strategies to reduce these errors, including discussion about how advances in technology may assist a radiation therapy provider in risk avoidance.

Regulation of Radiation Therapy

One reason cited for the low incidence of errors occurring in the delivery of radiation therapy is the strict regulatory environment surrounding this practice. Radiation therapy is regulated at both the federal and state level and is considered one of the most highly regulated medical practices. At the federal level, the Nuclear Regulatory Commission (NRC) regulates the use of radioactive materials.[9] On March 31, 2008, the Commonwealth of Pennsylvania entered into an agreement with NRC whereby the Department of Environmental Protection (DEP) took over regulatory authority for the possession and use of radiation materials and byproducts and other duties as authorized in section 274 of the Atomic Energy Act of 1954.[10,11]

In 1998, legislation was enacted in Pennsylvania requiring that all facilities with linear accelerators be licensed by the Commonwealth.[12] This licensing process allows DEP to evaluate and determine what requirements are necessary for the accelerator to be used safely in a medical facility. Pennsylvania has 126 facilities licensed with linear accelerators and is

one of several states currently requiring a licensing process. The Pennsylvania Department of Health regulates all hospitals and free- standing cancer therapy centers; however, the department authorizes DEP to license and inspect these facilities.

The U.S. Food and Drug Administration regulates the manufacturers of medical devices and other products that emit radiation and has published regulatory standards for medical x-ray equipment safety and performance. It has no legislative authority to regulate users of these devices, with the exception of facilities that perform mammography.[13]

Although nonregulatory in nature, the Conference of Radiation Control Program Directors is a nonprofit agency that serves as a common forum for many government radiation protection agencies to communicate with each other and promote uniform radiation protection regulations and activities.[14] Finally, the Joint Commission now focuses on this issue and revised its definition of a sentinel event in 2006 to include the delivery of radiotherapy to the wrong body region or delivery of greater than 25% more than a planned dose.[15]

Errors in Radiation Therapy

In the Commonwealth of Pennsylvania, events related to errors in the administration of radiation therapy are reported to two statutory bodies: the Pennsylvania Patient Safety Authority and the Pennsylvania DEP. It was noted in review of both data sets that the overall number of reports is low. According to Joseph Melnic, radiation protection program supervisor, Pennsylvania DEP, Bureau of Radiation Protection, these low rates may be attributed to the safety measures and advances in computerized technology.[16] It is unclear whether events reported to the Authority were also reported to the Pennsylvania DEP, so similar events may have been reported to both organizations. Although little has been published regarding error rates in radiation therapy, a study conducted by Macklis et al. at the Cleveland Clinic in 1995 reviewed 1,925 patients who were treated with a total of 93,332 individual radiotherapy fields. The study revealed a crude radiation delivery error rate of 0.18%.[2]

Pennsylvania Patient Safety Authority Data

Act 13 of 2002 requires all hospitals, ambulatory surgical facilities, birthing centers, and abortion facilities to report Serious Events and Incidents to the Authority. Table 1 shows the number of radiation oncology events reported to the Authority from June 2004 through January 2009. The Authority received 25 reports of radiation oncology events during this period. Of these reports, 24 involved external beam therapy and 1 involved brachytherapy. Six events were categorized as Serious Events (adverse events resulting in harm to the patient), and 19 events were categorized as Incidents (near misses). The majority of events reported to the Authority involved a patient receiving the wrong dose of radiation (40%), with a wrong patient (16%), wrong location (12%), wrong side (12%), and wrong setup (8%) being the most predominant treatment errors (see Table 2). The following examples further detail the types of errors reported to the Authority:

[Transcription error resulted in the wrong dose to the patient.] The dosimetrist transcribed the radiation oncologist's prescription incorrectly to the planning system and then to the recording system, which caused the patient to receive 2.5 times the recommended dose.

[Radiation therapy provided to the wrong patient.] The patient was given one treatment of the wrong patient's treatment plan in radiation oncology. The patient was called by name in the waiting room and answered to a similar sounding name; the patient identified herself with the incorrect patient's picture on the computer screen in the treatment room and the staff did not catch the error. The treatment given was for another patient with a similar type of cancer [with a similar physical appearance]. This patient received 1 Gray less than the prescribed dose to the intended area. There was no harm to the patient. There was no clinical significance.

Table 1. Radiation Oncology Events Reported to the Pennsylvania Patient Safety Authority, June 2004 through January 2009

YEAR	NUMBER OF REPORTS	% OF TOTAL
2004	6	24%
2005	4	16%
2006	6	24%
2007	1	4%
2008	6	24%
2009	2	8%
Total	**25**	**100%**

Table 2. Radiation Oncology Event Types Reported to the Pennsylvania Patient Safety Authority, June 2004 through January 2009

TYPE OF ERROR	NUMBER OF REPORTS	% OF TOTAL
Wrong dose	10	40%
Wrong patient	4	16%
Wrong location	3	12%
Wrong side	3	12%
Wrong setup	2	8%
Wrong treatment	1	4%
Wrong treatment device	1	4%
Equipment other	1	4%
Total	**25**	**100%**

[Radiation therapy to the wrong location.] A non-English speaking patient with breast cancer was to have radiation treatments to the left breast. The patient received 15 treatments on the right breast before the error was recognized. The consent was signed for left breast. The prescription for treatments was written for the right breast.

Pennsylvania Department of Environmental Protection Data

In accordance with state code (25 Pa. Code § 219.3), facilities that are licensed or registered to deliver radiation therapy are also required to report a radiation therapy event to DEP when it meets the following definition:

Medical reportable event for radiation-producing machine therapy. The administration to a human being, except for an administration resulting from a direct intervention of a patient that could not have been reasonably prevented by the licensee or registrant, that results in one of the following:

(i) An administration of a therapeutic radiation dose to the wrong individual

(ii) An administration of a dose for therapy when the result is an increase in the total expected doses inside or outside the intended treatment volume for organs, tissue, or skin that exceeds 20% of the total prescribed dose for the intended target volume

(iii) A total dose delivered to the treatment site identified in a written directive for therapy that is outside the prescribed dose range or differs from the total prescribed dose by more than 20%, or for a fractionated dose, when the weekly administered dose differs from the weekly prescribed dose by more than 30%[17]

From February 2004 through January 2009, 35 medical events were reported to DEP (see Table 3). An exact total number of radiation therapy procedures performed per year in Pennsylvania is not available; however, Melnic estimates that up to 1 million radiation therapy treatments are given each year in Pennsylvania. Melnic noted that the number of medical events reported to his department has been decreasing in recent years and attributes the reduction in medical events to increases in computerized technology in conjunction with the licensing program mentioned previously.[16] Analysis of the DEP data reveals the predominant type of medical event reported involved the patient receiving radiation therapy to an incorrect site (46%), followed by a wrong patient being treated (27%), and a patient being given the wrong dosage of radiation therapy (21%) (see Table 4), which is consistent with the Authority's data.

Radiation Oncology Safety Information System

The Radiation Oncology Safety Information System (ROSIS) maintains a database of radiation therapy events. This voluntary Web-based safety information database was established in 2001 and currently holds approximately 700 reports from 19 countries. In January 2007, a sample of the report generated by ROSIS included a spotlight on data transfer errors. At that time, 294 of 600 events reported (49%) were considered to have an element of data transfer that caused or contributed to the occurrence of a radiation therapy event. Of the events reported, 130 of the 294 resulted in the patient getting the incorrect treatment. Fifty-three percent of the errors were discovered during a chart check, with 34% being found at the time of patient treatment.[18]

Risk Reduction Strategies

As noted above, the most common radiation misadministrations have resulted in patients receiving a wrong dose of radiation therapy, delivery of radiation therapy to a wrong site, or patients receiving the wrong treatment plan. Risk reduction strategies discussed will address an advancing role of technology in preventing errors as well as utilization of other patient

Table 3. Medical Accelerator Events Reported to the Pennsylvania Department of Environmental Protection, Feburary 2004 through January 2009

YEAR	NUMBER OF REPORTS	% OF TOTAL
2004	6	17%
2005	9	26%
2006	7	20%
2007	6	17%
2008	6	17%
2009	1	3%
Total	**35**	**100%**

Source: Pennsylvania Department of Environmental Protection, Bureau of Radiation Protection. [reports of medical accelerator events]. E-mail to: Pennsylvania Patient Safety Authority. 2009 Apr 2.

Table 4. Medical Accelerator Event Types Reported to the Pennsylvania Department of Environmental Protection, February 2004 through January 2009

TYPE OF ERROR	NUMBER OF REPORTS	% OF TOTAL
Incorrect site	17	46%
Wrong patient treated	10	27%
Incorrect dosage	8	21%
Underestimated medical procedure duration	1	3%
Inattention to detail	1	3%
Total	**37**	**100%**

Source: Pennsylvania Department of Environmental Protection, Bureau of Radiation Protection. [reports of medical accelerator events]. E-mail to: Pennsylvania Patient Safety Authority. 2009 Apr 2.

safety protocols, such as patient identification processes, to ensure the patient receives the prescribed therapy.

Reducing Radiation Therapy Errors through Emerging Technology

Delivering the prescribed dose of radiation to the patient remains the top goal as deviations in prescribed dose by more than 5% may influence the outcome of treatment.[19,20] Technology associated with delivering radiation therapy has advanced greatly during the last decade.[5,21] The manual processes of planning and delivering radiation therapy are being replaced by computerized systems for electronic order entry, treatment plan development, and review and verification of coordinates at the time of treatment.

Most linear accelerators use a computerized record and verify (RV) system. RV systems have been used since the 1970s and are successful at reducing the number of misadministration errors while allowing for delivery of complex treatment plans.[22] RV systems verify that treatment parameters entered are the same that are set to be delivered to a patient. If these parameters do not match, then the external beam is inhibited from firing.[4] Though RV systems have been found to help reduce the errors in radiation delivery, they are not used in every facility. In Pennsylvania, all linear accelerators have computerized RV systems, with the exception of a few grandfathered devices, according to DEP.[16] While reducing overall errors in radiation therapy, use of RV systems has created some new types of errors.[5,7] A study conducted by Patton et al. from 1999 to 2000 at the University of Utah showed radiation therapy staff had an overreliance on RV systems. During that 1-year period, this study showed that of 22,542 external beam radiation therapy treatments administered, 38 treatment errors were identified (0.017%). Nine of these events involved errors related to the use of the RV system. Identified errors included a wrong patient being treated, an incorrect data file being used by means of a staff override of the system, an incorrect site being treated, and incorrect beam modification.[7] Another study conducted by Leunens et al. in 1990 reported that nearly half of all major deviations (more than 5% from prescribed treatment) were introduced during the manual input of data into the RV system. This study showed that these human errors would lead to greater systematic errors if not caught.[20]

Computer-controlled delivery systems have led to a decrease in errors while allowing for more complex treatment plans to be delivered, without increasing treatment time.[22] Fraass et al. explains that computer-controlled delivery systems have three main aims: (1) make treatment delivery more efficient, (2) improve accuracy of treatment, and (3) make new and more complex treatment modalities, such as intensity modulated radiation therapy, possible even as facilities continue to try to improve cost efficiency.[22] A 15-month study conducted between 1996 and 1997 by Fraass et al. found an error rate of 0.21% for all manually treated cases and an error rate of 0.085% for all computer-controlled cases.[22] While computer-controlled treatment plans reduce the rate of random treatment delivery errors, they may be susceptible to systematic errors, which may be hard to detect. New technology creates new types of errors when staff do not have proper knowledge or training regarding new equipment, resulting in the utilization of workarounds when encountering system errors.[23] In addition, quality assurance (QA) testing must be done to ensure that the computers are working appropriately.[23] Methods of performing QA as recommended by such groups as the American Association of Physicists in Medicine (AAPM) predate technologic advances such as image-guided radiation therapy, computer-controlled linear accelerators (linacs), RV systems, electronic medical records, and use of digital imaging.[23] The increasing complexity of modern radiation therapy planning and delivery techniques challenges traditional prescriptive QA programs as they are consuming more resources than facilities have available. In this current environment, the number and sophistication of possible tests and measurements have increased dramatically. Task Group 100 of the AAPM is developing a framework for designing QA activities and will provide guidelines on risk assessment approaches with emphasis on failure mode and effects analysis.[24]

Checking and Double Checking before Radiation Therapy Is Delivered

Ensuring that a patient receives the prescribed dose of radiation therapy occurs in several different ways. Performing independent checks of therapy treatment plans is considered an integral part of the therapy verification process. The American College of Radiology recommends all radiation therapy plans undergo an independent double check and be signed by a radiation oncologist within one week of treatment initiation.[1] An Australian study conducted by Duggan et al. examined the efficacy of performing an independent double check of radiation therapy treatment plans (check of prescription, choice of beam, and dose calculations) From 1993 to 1995, 1,579 patients were treated, 2,328 treatments plans were reviewed, and 235 interventions or changes were made. Of these 235, the majority of the interventions were minor in nature and only 6 fell into the category of major errors that would have resulted in the patient receiving a dose of greater than 10% of the intended dose. Although the checks were found effective, these study authors estimated that staff needs would increase by 0.3 full-time staff per 1,000 patients per year to provide these checks.[25]

Although not unique to radiation therapy, proper patient identification procedures need to be in place and strictly followed. In both the Authority and DEP reporting system databases, events involving patients receiving therapy prescribed for other patients were noted. Joint Commission's National Patient Safety Goals state that at least two patient identifiers will

be used when providing care to a patient.[26] This information should be confirmed with information in a patient's medical record. Even though the Joint Commission excludes radiation oncology from the Universal Protocol standard,[27] radiation therapy staff should consider performing a final verification, which may include verification of patient's identity (two identifiers); verification of the site of treatment, including laterality as compared to the digitally reconstructed radiograph and port films; and comparison to the consent and treatment plan.

Lastly, in vivo dosimetry has been established as a reliable method for verification of external beam therapy. It is defined as dose measurements performed on patients during the delivery of radiation therapy. This process is accurate and may be effective in minimizing errors resulting in 5% or more being delivered but can be costly and time-consuming if used on every patient. Most departments select which group of patients on which they will use this process to ensure timely and efficient use of resources.[25] An in vivo dosimetry program should be considered for QA of machine calibration, planning dosimetry and dose calculation, patient setup, and influence of beam modifying components. [28]

Conclusion

Radiation therapy is a highly regulated, complex treatment modality that is performed on approximately half the patients diagnosed as having cancer. Error rates associated with delivery of radiation therapy are low, as are reports of injury to patients. This discipline of medicine is subject to strict regulatory and quality control standards. Safety in delivery of radiation therapy has been a result of advances in computerized technology, which reduces many errors associated with manual preparation and delivery of radiation therapy. Radiation therapy providers must be proficient when utilizing these new technologies. In addition, providers must perform effective independent double checks not only of treatment plans but also of patient identification and site verification.

Notes

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