

Safe and Judicious Use of Advanced Radiotherapy Techniques and Equipment: A Medical Physicist's Perspective on Recent Accident Reports

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Radiotherapy (RT) is a well-established modality for treatment of cancer. The efficacy of RT has been demonstrated for many cancers in a number of clinical trials.¹ In recent years, substantial technological advances have made possible the implementation of such complex and sophisticated RT techniques that merely two decades ago would have been considered by most as 'science fiction'. Such techniques were generally first developed and used at well-known RT centers of excellence and then disseminated to smaller clinics. Given this renaissance, recent media reports on a large number of errors related to the RT given to patients have caused significant concern within the RT community as well as with patients and the authorities. The aim of this editorial is to briefly introduce some of the main recent technological advancements and their clinical benefits, and then highlight the need for the due care and attention that is required when complex technologies

are introduced into the clinic. This is presented here with emphasis on the needs and status of RT in the Middle East and from the perspective of a medical physicist.

The technology-led revolution in radiotherapy

During 1990s and 2000s, several developments reached a stage where a number of highly advanced commercial equipment became available. Such technologies (and the techniques utilizing them) have created a platform for substantial leaps in the level of customization, flexibility and detail that can be applied in the planning and delivery of RT to patients. For example, multileaf collimators have facilitated field shaping to conformally fit the radiation field to the target with the purpose of improved sparing of normal tissues. Electronic portal imaging devices have allowed patient imaging on the treatment table to ensure that the patient is positioned exactly as originally planned. The

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technique of intensity-modulated radiotherapy (IMRT) has enabled the realization of an even tighter dose conformation to concave-shaped targets and other flexibilities, such as treating various volumes to different dose levels or producing a homogeneous target dose despite complex tissue contour irregularities and density inhomogeneities. In image-guided RT, target and normal tissue motion and changes during the course of the multi-week treatment and even within each treatment session (fraction) can be determined and their effects taken into account. Robotic treatment machines, CT-like tomotherapy and other such recent developments in treatment delivery have offered even more choice and flexibility, each with its own set of advantages. In addition to the more conventional electron beam RT, facilities to treat using heavier particles (especially protons) have become increasingly available to take advantage of their sharper dose fall-off beyond the target to better spare normal tissues. More advanced imaging modalities, including those offering functional and molecular imaging have assisted with the highly important task of determining the true extent of the tumor in the first place. There are several other advanced technologies and methods; however it is certainly not the aim of this editorial to present a review of the developments in RT. Several such reviews have been published elsewhere.²⁻¹¹

The above-mentioned developments coupled with increased knowledge of radiation biology and patient outcomes and better integration of RT in multi-modality treatment regimens have provided potentially superior treatments in terms of tumor control and/or normal tissue toxicity. Some clinical improvements resulting from technical advancements have already been observed and reported. For example, in prostate cancer RT, reduced normal-tissue side effects¹²⁻¹⁴ (e.g., rectal bleeding) or improved survival as a result of target dose escalation (made possible by the potential for better normal-tissue sparing)¹⁵ have been reported, while dose escalation with a less advanced conventional RT technique had previously produced unacceptable side effects.¹⁶ Similar

results have been found in other cancers including head and neck, lung, breast, liver, and brain.¹⁷⁻²²

The role of medical physicists

Medical physics involves the application of the concepts and methods of physics to the diagnosis and treatment of disease. Among the various fields in which medical physicists are active, RT is the primary discipline for the largest number of medical physicists.²³ Medical physicists are often involved in academic teaching and research but the majority of them primarily have clinical responsibilities.²³ Medical physicists have had a major role in the above-mentioned developments, often formulating the initial ideas and then producing the required methods, algorithms and procedures. A medical physicist mainly working in clinical RT is sometimes referred to as a clinical RT physicist. Such a professional can be thought of as a guardian of the quality (accuracy and precision) of the amount and distribution of the radiation dose delivered to the patient. This is mainly achieved by performing radiation dosimetry, dose calculation, quality assurance (QA) and radiation safety procedures. The role of a clinical RT physicist is, therefore, crucial in preventing errors in dose delivery to patients and in fact, his/her involvement in assessing and approving the quality of radiation treatment is mandated by regulatory bodies.

Reports of accidents in radiotherapy

During recent months, there has been a notable increase in the number of media reports regarding errors and accidents in radiotherapy centers, primarily in the United States.²⁴ Such accidents can be due to human error or equipment malfunction and may lead to target underdosage or normal-tissue overdosage for individual patients or, in some cases, a number of patients over a period of time. These errors are rare but there is concern that they are underreported. Several well-known and respected organizations including the International Atomic Energy Agency (IAEA), International Organization for Medical Physics (IOMP), American Society for Therapeutic

Radiology and Oncology (ASTRO), American Association of Physicists in Medicine (AAPM) and others have expressed concern.

Some of these accidents appear to be due to equipment problems. In April 2010, in a letter to manufacturers of linear accelerators, RT treatment planning systems and ancillary devices²⁵, the United States Food and Drug Administration (FDA) stated: "in order to reduce the number of under-doses, over-doses, and misaligned exposures from therapeutic radiation, the FDA is taking several steps to improve the safety and safe use of certain radiation, therapy devices". The letter added: "analyses of Medical Device Reports (MDRs) revealed device problems that appear to be the result of faulty design or use error that could be mitigated by the incorporation of additional safeguards" and that "between December 31, 1999, and February 18, 2010, FDA received 1,182 MDRs associated with the use of radiation therapy devices", the most frequently reported device problems being "computer software issues, use of device, and incorrect display".

Generally, it seems logical that greater complexity in the equipment and techniques used in RT increase the probability and variety of errors and malfunctions that may occur, and that special QA solutions are often necessary to check for them.²⁶⁻²⁹ Moreover, as the developments in complex radiation delivery techniques were being made during the 1990s, medical physicists were working in parallel to improve the methods of checking how accurately they could deliver the dose to patients by means of electronic portal imaging, cone-beam CT, dynamic IMRT verification, etc.³⁰⁻³⁵ However, such QA and verification requires additional resources (both human and monetary) and failings in this regard may well have contributed significantly to the problem, although the author is not privy to detailed information on this matter and neither intends, nor is in a position to, pass judgment on it.

The Middle Eastern viewpoint

In terms of availability of modern equipment,

RT centers in the Middle East form a wide spectrum. Some centers have the most up-to-date systems, some are in the process of acquiring, installing or commissioning them and others are planning to do so. In the author's opinion, these centers should try to avoid overreliance on equipment, no matter how well-known and established the manufacturer may be. The duty falls not only on the shoulders of the clinical RT physicists, but also on the hospital administration, radiation oncologists and RT technologists to recognize the magnitude of the problem and act accordingly. Financial and other considerations can lead to undue pressure put on physicists to shorten the equipment acceptance and commissioning processes. An insufficient number of RT centers and/or staff shortages can result in overworked professionals having to cut corners. The personnel involved may not even be fully trained. For instance, the requirements for a Qualified Medical Physicist whose work impacts patient treatment is well defined.²³ A physics or radiation-related university qualification on its own is deemed insufficient. The entire clinical, physics, engineering and technologist staff should undergo sufficient training and subsequently participate in appropriate continuing medical education or continuing professional development programs. There is currently a wealth of information and guidance available to health professionals in RT from a wide range of organizations, such as those mentioned above, as well as others such as the International Commission on Radiological Protection (ICRP), European Society for Therapeutic Radiology and Oncology (ESTRO), Institute of Physics and Engineering in Medicine (IPEM) and Royal College of Radiologists (RCR).

There is no doubt that the new advancements have reinvigorated the fight against cancer and have given us more ammunition to do so. The centers implementing these advancements in this region should, however, do so safely and judiciously. We should try to learn from what has happened elsewhere and use the best examples of how to proceed. In the author's own experience working at the Royal Marsden Hospital and

Institute of Cancer Research (University of London, UK), starting patient treatments for IMRT was limited to one patient per week for a considerable period (to allow meticulous and customized checking of all the relevant aspects of the treatment planning and delivery) until sufficient confidence was gained to increase the number of patients offered this treatment. This was in contrast to some centers elsewhere in the world where this complex treatment was given at a much greater rate but with a lower level of QA and verification. It seems unwise to approach the task of implementing such complex technologies for patient treatment in a purely technophilic way without the safeguards to ensure that no harm is done to our patients.

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