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QUALITY ASSURANCE IN RADIOTHERAPY FOR CANCER TREATMENT: AIMING TO IMPROVE PATIENT SAFETY

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ABSTRACT

The process of radiotherapy (RT) is complex and involves an understanding of the principles of medical physics, radiobiology, radiation safety, dosimetry, radiation treatment planning, simulation, and interaction of radiation with other treatment modalities. Each step in the integrated process of RT needs quality control and quality assurance (QA) to prevent errors and to give high confidence that patients will receive the prescribed treatment correctly. Recent advances in RT, including intensity-modulated and image-guided RT, focus on the need for a systematic RTQA program that balances patient safety and quality with available resources. It is necessary to develop more formal error mitigation and process analysis methods, such as failure mode and effect analysis, to optimize available QA resources on process components. External audit programs are also effective. To strengthen procedures and ensure the dosage from RT equipment, the International Atomic Energy Agency has run both an on-site and off-site postal dosimetry audit. National clinical auditing has been practised in other nations using a similar strategy. Additionally, clinical trial quality assurance plays a key part in raising the standard of treatment. The creation of an infrastructure and QA procedure for clinical trials including advanced technology, including accreditation and individual case reviews, was pioneered by the Advanced Technology Consortium. These initiatives, which have been implemented internationally by the USA, Europe, and Japan as well, have an effect on the quality of care provided to all patients treated in each institution as well as the therapy received by patients involved in clinical trials.

KEYWORDS: Radiation therapy, Quality assurance, Radiation dosimetry, Clinical audit, Clinical trial.

INTRODUCTION[1-3]

The ultimate overall goal of radiotherapy is to deliver a specified radiation dose to the prescribed target volume with the least dose to healthy tissues. This means a sophisticated balance between the cure of the illness and the possibility of radiation induced complications. The demands for precision and accuracy are high, because very often a small increase in radiation dose will have crucial influence on the probability of a cure but simultaneously the probability of induction of irreversible damage to the patient will increase. Radiotherapy (RT) is one of the major options in cancer treatment. It is a multimodal therapy used in conjunction with chemotherapy and/or surgery to treat cancer. In cases of advanced or recurring cancer, radiation therapy is also a very useful choice for symptom management and palliation. Only a quarter of cancer patients in Japan get radiation therapy, despite the fact that the majority of patients (52% of them) should do it at least once. It is important to grasp the fundamentals of medical physics, radiobiology, radiation safety, dosimetry, RT planning, modelling, and the interplay of RT with other therapy modalities since the process of RT is intricate. Radiation oncologists, medical physicists, radiation technicians, and radiation nurses make up the expert team for RT. To plan and provide RT to cancer patients, these experts use a coordinated strategy. The sequential process is shown in Fig. 1 and each step needs quality control (QC) and quality assurance (QA) to prevent errors and to give high confidence that patients will receive the prescribed treatment correctly. Photon-based radiotherapy (RT) techniques have evolved enormously since the introduction of computerized axial tomography (CT) scanning in RT planning 30 years ago. Since then, external beam RT has evolved from two-dimensional (2D) conventional RT to 3D conformal RT, then static beam intensity-modulated RT (IMRT), and ultimately to rotational IMRT or volumetric modulated arc therapy (VMAT). IMRT is a technique that combines irradiation beams with non-uniform fluence intensity to generate steep dose gradients even in target volumes (TVs) with a concave shape. As a direct consequence, TVs are treated more homogeneously and with a better sparing of the nearby organs at risk (OARs), in comparison with the classical 2D or 3D RT techniques. This better sparing of the OARs is particularly relevant in areas of the body where there are relatively radioresistant TVs in close vicinity to radiosensitive OARs, such as in the head and neck area. Because IMRT has been shown to be superior to 3D conformal RT in terms of preventing xerostomia, it has consequently established the gold standard of care for the treatment of head and neck cancer (HNC). Intensity-modulated proton therapy (IMPT), a recently developed technology, has being investigated for its potential to minimise side effects in HNC patients beyond what is possible with IMRT utilising photons. Since the exact placement of the distal border of the Bragg peak is unknown, IMPT may be more susceptible to changes in patient setup, CT scan results, and patient anatomy than IMRT.

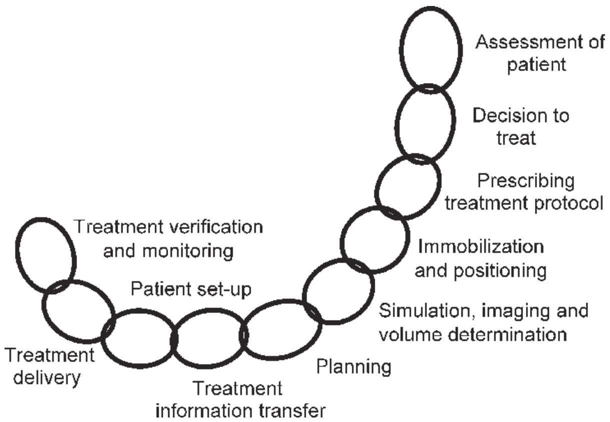

Figure 1: Sequential process of planning and delivering radiotherapy to patients.

CLINICAL TRIAL QA[4-7]

In the USA, RTQA programs have been developed mainly through clinical trial QA. Since 1968, the National Cancer Institute (NCI) has continuously sponsored the Radiological Physics Centre (RPC) to offer high-quality audits of dosimetry procedures at institutions taking part in NCI cooperative clinical studies. The RPC's main duty is to ensure that all participating institutions have the tools, staff, and protocols required to deliver radiation doses that are clinically equivalent and consistent for the NCI and the cooperative clinical trial groups. On-site dosimetry evaluations, remote auditing tools like TLD and anthropomorphic phantoms, as well as analyses of benchmark and real protocol patient treatments are some of the monitoring methods that are employed. By 2007, the RPC was keeping an eye on about 1500 RT institutions. To assist the institution in resolving discrepancies found by the RPC, an investigation is conducted. The RPC's overall RTQA programme affects both the quality of care provided to all patients at the facility as well as the care given to those involved in clinical trials.

The Radiation Therapy Oncology Group (RTOG), RPC, QA Review Centre (QARC), and Resource Centre for Emerging Technologies are members of the NCI-sponsored Advanced Technology QA Consortium (ATC), which has pioneered the development of an infrastructure and QA method for advanced technology clinical trials that call for volumetric digital data submission of a protocol patient's treatment plan and verification data. Particularly in regards to simplifying the QA evaluation for RTOG advanced technology clinical trials, the ITC has over 15 years of expertise. This QA process includes (i) a data integrity review for completeness of protocol-required elements, the format of data, and possible data corruption, and recalculation of dose–volume histograms, (ii) a review of compliance with target volume and organ-at-risk contours by study chairs and (iii) a review of dose prescription and dose heterogeneity compliance by the RTOG Headquarters Dosimetry Group.

Additionally, before taking part in clinical studies, institutions must receive qualifications. The ITC and RTOG introduced two concepts: (i) a facility questionnaire that outlines the technical capabilities of the organization and identifies the key members of the treatment team; and (ii) a series of protocol-specific tests, such as an electronic data submission test and a dry-run test, to show comprehension of the protocol planning and data submission requirements. Additional accreditation exams are necessary for new modalities including stereotactic body radiation therapy (SBRT) and IMRT. A localization credential test has been built for SBRT procedures to evaluate the consistency of the patient setup, and the RPC designed a postal anthropomorphic phantom (Fig. 2) that incorporates dosimeters to test the delivery capabilities of the institutions' IMRT systems. Reducing the deviation rate for data submitted to clinical trials is the main objective of credentials. According to RPC research, cooperative groups have occasionally seen deviation rates of as high as 17% of the cases filed.

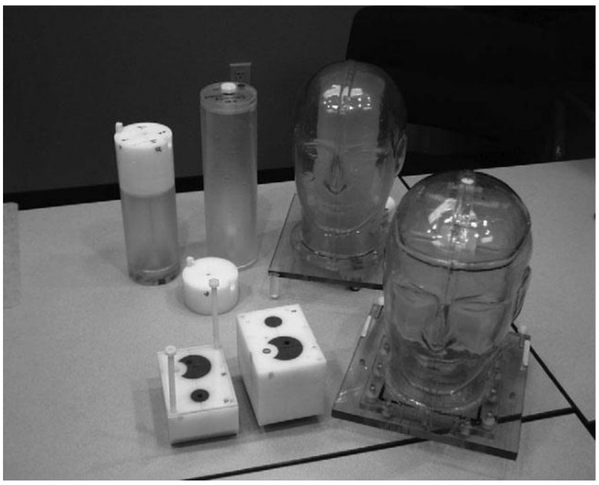

Figure 2: The Radiological Physics Center postal anthropomorphic phantom.[8-9]

Europe and Japan have both embraced these practices. The European Organisation for Research and Treatment of Cancer (EORTC) RT Group initiated RTQA programs as early as 1982. Over the course of 25 years, QA processes have expanded to encompass a sizable and significant portion of the group's activities. After two consecutive audits, the radiation dosimetry quality assurance program showed that significant photon and electron beam calibration discrepancies had vanished. RT routine practice in Europe currently follows this paradigm as standard practice. In Japan, the Japan Clinical Oncology Group (JCOG) initiated clinical trial RTQA programs in 2002 as a result of the findings of a phase III study that showed poor protocol compliance (40%). The first study (JCOG 0202) that requires ongoing RTQA had excellent protocol compliance according to newly released QA results. The JCOG is also working with the ATC and EORTC to create a global standard for high-tech clinical trial quality assurance. The ATC is supporting JCOG 0403, a phase II SBRT study for stage I non-small cell lung cancer, and utilizing a web-based remote review tool, individual case evaluations are being carried out (Fig. 3).

Figure 3: Advanced Technology Quality Assurance Consortium remote review tool.[10]

THE COST OF QA[11]

Data on the costs associated with RT QA are scarce due to the practical difficulties associated with carrying out economic studies in this field, in terms of cost calculation and efficacy data. Although one may anticipate that more/higher-level QA will increase overall costs, the contrary might be true. In a simulated investigation, Weber et al. demonstrated that raising QA levels resulted in improved overall survival and a lower risk of tumour recurrence in a prospective HNC trial. They discovered a link between the patient's outcome and the complexity of the QA procedures, which led to a reduced overall cost for more complicated and hence more expensive QA since there were fewer recurrences and consequently less expenses for repeat treatment. Without adding to the expense of treatment, it is also possible to enhance patient outcomes concurrently. Simons et al. revealed the cost-effectiveness and increase in patient outcomes observed after lowering the waiting periods before starting therapy (important for HNC patients). With their new process, waiting times were cut from 5 days for patients with oropharyngeal or hypopharyngeal cancer to 22 days for patients with laryngeal cancer, adding 0.13 to 0.66 more years of quality-adjusted life. Some RT centres could be discouraged from implementing a higher level of QA since greater QA expenses frequently need to be covered by the RT department or hospital while the advantages (better outcomes) are seen by society or the government. In order to properly cover these treatment-specific increased QA costs, measures should be made.

IMPORTANCE OF QA IN OTHER ASPECTS OF TREATMENT[12]

Increasing awareness of the importance of QA and of centralization remains largely restricted to the RT aspect of HNC treatment. More and more data are converging to illustrate that the outcome of patients with HNC is better when performed in large-volume centers compared to low-volume centers. This discovery most certainly has several causes, including the quality of RT planning and delivery as well as the reliability of other stages in tumor staging (such as pathology and imaging) and treatment (such as surgery and systemic therapy). The ability of the doctor and hospital to respond to changes and occurrences that arise during the patient's course of treatment is also crucial, as is the effective integration of these phases into the patient care pathway.

RESULTS[13]

Between December 2000 and February 2004, 24 patients from eight Japanese hospitals were enrolled. Table I displays the main locations and patient characteristics. Three patients, who each had just two rounds of chemotherapy, did not follow the research protocol. Following these three patients' departure from protocol, radiation was administered to all 24 enrolled individuals. In contrast to one situation where the QA committee was unable to obtain the data, data from 23 cases were accessible for QA evaluation.

Table I: Patient characteristics.[14]

Characteristics	No. of patients	(%)
Age, years		
Median	75	
Range	70-84	
Location		
Waldeyer's Ring	11	(46)
Neck node	6	(25)
Maxillary sinus	3	(13)
Thyroid	2	(8)
Parotid gland	1	(4)
Paravertebral area	1	(4)
Stage		
I	16	(67)
II	8	(33)
Tumor size		
<6 cm	19	(79)
6 cm≤, <10 cm	4	(17)
≥10 cm	1	(4)

CONCLUSION[15]

In order to give the correct dose at the precise right location to maximise tumour control and minimise toxicity, thorough QA is crucial at every stage of the RT route due to the growing complexity and accuracy of contemporary RT procedures, particularly for HNC. As a result, RT QA should include frequent end-to-end testing, external audits, and a defined program to methodically manage each stage in the route in both ordinary practice and clinical trials. In order to fully realize the advantages associated with the provision of safe, standardized, and high-quality patient care, this QA should ideally not just include RT but also every step of the patient route.

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