Continuous Quality Improvement in Radiotherapy: the experience of the Italian National Institute of Health

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Abstract. The Italian National Institute of Health (ISS) with government financial supports has started some programs of collegial accreditation in the field of radiotherapy. Purpose of this activity is the developing and testing of tools that allow examination and evaluation through a systematic review of the radiotherapy activities. In parallel with the evaluation activity the ISS is continuously developing guidelines for quality assurance in radiotherapy. These guidelines, jointly developed by radiation oncologists, medical physicists and radiotherapy technicians from Italian Centres of radiotherapy and of medical physics, may help operators in obtaining thresholds or standards. Parallel activities are concerning the developing of indications for total body irradiation and for ethical problems in clinical trials involving radiation therapy protocols. Finally, dosimetric intercomparisons in both reference and non reference conditions have started.

1. Introduction

The healthcare organisations are moving from the concept of quality assurance to that of continuous quality improvement. In recent years, the Italian National Institute of Health (ISS) with government financial support has started some programs of collegial accreditation in the field of radiotherapy. Purpose of this activity is the developing and testing of tools that allow examination and evaluation through a systematic review of the radiotherapy activities. Clinical indicators are recognised as an efficient tool to this purpose as their introduction into an accreditation program offers an objective measure of clinical management and outcome of care. Furthermore they may facilitate the collection of national data on which standard can be created and performances of the Centres with respect to the national level evaluated. Special audits on clinical indicators (see related communication) have been implemented.

To define reference systems is not always an easy task. In fact, an audit compares performances of the Centre against thresholds and/or national aggregate data. The aim of the development of indicators is not only that of the surveying of patient care processes and outcomes, but also to facilitate the collection of national data on the processes and outcomes. The creation of databases is therefore also an important goal of the audit based on evaluation indicators. Furthermore, in parallel with the evaluation activity the ISS is continuously developing guidelines for quality assurance in radiotherapy. These guidelines, jointly developed by radiation oncologists, medical physicists and radiotherapy technicians from Italian Centres of radiotherapy and medical physics, may help operators in obtaining thresholds or standards. Guidelines have been elaborated on general subjects (comprehensive guidelines for quality assurance in radiotherapy and for quality controls) as well as on special techniques (quality assurance in total body irradiation, in intraoperative radiotherapy, in brachytherapy).

Finally, audit for dosimetry have started. Reference and non reference (treatment of the rectum according to national guidelines of radiation oncologists) conditions have been considered. Indicators of the accuracy in dose delivery are currently being defined. A dosimetric audit for intraoperative radiotherapy has been also planned and will start in the current year.

2. Guidelines elaboration

In parallel with the evaluation activity the ISS is continuously developing guidelines for quality assurance in radiotherapy. A recent document for quality assurance in radiotherapy presents
comprehensive national guidelines and, in particular, contains the professional profiles, roles and responsibilities, personnel and equipment requirements as well as the main items of the procedures. A second document on conformal radiotherapy is in progress. Finally, indications were given to elaborate quality manual for radiotherapy and connected medical physics activities. This last document contains the main principles of the quality policy, the role of the quality manual in a continuous quality improvement program and a scheme to elaborate procedures for the process of external beam therapy are reported. These documents accompany Italian guidelines elaborated by professional associations such as those of the radiation oncologists and of medical physicists. All this documents may constitute reference material in developing the indicators and performing the clinical audit.

3. Ethical problems

A special attention has been devoted to the specific ethical problems that may arise in clinical trials involving radiation therapy protocols. Ethics Committees, set up in accordance with national laws, are asked to evaluate medical exposure for biomedical and medical research, mostly related to pharmacological research. The Committees are also specifically asked to evaluate clinical protocols conducted with ionising radiation and to verify optimisation and justification of radiation exposure. This task requires the presence of the proper professional skills in the evaluating procedure. A relevant problem is also quality in performance of the irradiating devices and homogeneity of the procedures when dealing with multicentric clinical trials. Definition of the adequate requirements is therefore necessary. A document devoted to these aspects of clinical research in radiation therapy is in progress with the contribution of the different professionals involved.

4. Programs in the field of quality assurance for total body irradiation (TBI)

As first step in this field, we have developed guidelines. During their elaboration, the necessity of paying particular attention to the problem of follow up appeared as question of great relevance. Particularly, we are paying attention to the definition of indicators for TBI in bone marrow transplantation. In this case, the follow up of the patient is performed by the haematologists and their involvement is necessary to define correct indicators. We have started a project that considers the collection of databases to monitor efficacy and toxicity of TBI as first step. The early and late toxic effects as well as the effectiveness of transplantation are examined in parallel with the examination of TBI parameters.

4. Dosimetric intercomparisons

In the framework of the ISS activity in the field of Continuous Quality Improvement in Radiotherapy, a pilot programme of dosimetry intercomparison among 16 Italian Radiotherapy Centres for high energy photon beams has been performed during 2002. Based on the positive experience of the pilot project, the Italian Minister of Health approved the extension of the audits to other 22 Italian Radiotherapy Centres for the next two years. Moreover, a special programme of dosimetry audits has been approved for Intra-operative Radiation Therapy (IORT) modality that will start in 2004. The Italian intercomparisons, with respect to others currently running at national or international level, has two main peculiarities. The first is related to the requirement of checking the accuracy in the dose delivered not only under reference conditions but also for a simulated treatment. In the reference conditions transfer dosimeters have been irradiated in a water phantom. In the treatment conditions a rectum cancer treatment has been simulated, delivering the dose to an anthropomorphic phantom. Centres were asked to perform the treatment planning process (CT scans, dose calculation, plan implementation, etc.) before dose delivery. The isocentre static technique with four opposing fields has been chosen for phantom treatment. The second peculiarity relates to the use of the alanine/EPR (electron paramagnetic resonance) dosimetry system, instead of the widespread thermoluminescence, for dose measurement. The absence of energy dependence in high energy photon beams, absence of fading, 1% (1s) accuracy, robustness for mail delivery and non-destructive read-out procedure are the main characteristics that substantiated the choice of alanine. Alanine dosimeters were used for dose assessment in the reference point in
water and in the isocentre point in simulated treatment conditions in anthropomorphic phantom. Irradiation to 10 Gy was required for alanine to assure 1% uncertainty. Also TLDs (TLD-100, Harshaw) were used for dose distribution measurements in 6 selected points in the anthropomorphic phantom, five within PTV and one outside, in correspondence of bladder. In this case the required dose at the isocentre was 1 Gy.

As for IORT, mobile dedicated facilities, located in the operating room, are largely used in Italy (at present 11 dedicated accelerators) with respect to the total number of accelerators used for IORT (16 in total). Both conventional and mobile linear accelerators present peculiar dosimetric aspects. In the first case, the use of IORT cones increases the diffused electron component leading to a modified energy spectrum (towards lower energy components) and to a wider angular distribution with respect to the conventional collimators. In this case, the use of dosimetry protocols such as IAEA TRS 398 may lead to an additional uncertainty component in dose of about 1%. In the second case, dosimetry of electron beams delivered by the mobile linac, characterised by much higher dose per pulse values (2-12 cGy/pulse) than traditional machines (about 0.06 cGy/pulse), cannot be performed on the basis of any existing dosimetry protocols, since ionisation chamber cannot be used due to the uncertainty in the determination of the ion recombination factors. It was so recognised and stressed the need to perform dose audits for IORT. Dose checks will be performed using IORT cones of different dimensions and base-bevelled applicators. Alanine will be used as the transfer dosimeter.

The Physics Laboratory of ISS acts as the co-ordination and measuring centre in collaboration with the Italian Primary Standard Dosimetry Laboratory INMRI/ENEA which assures traceability of the transfer dosimetry system to primary standards.