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Quality assurance in radiotherapy: from radiation physics to patient- and trial-oriented control procedures

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Abstract

The stepwise process of the EORTC Quality Assurance Programme in Radiotherapy is described in function of two main criteria: the targets of the quality control procedures implemented, in Radiation Physics and clinical research, by the EORTC Radiotherapy Group and the development of both trial- and patient-oriented quality systems. This exhaustive program, which started in 1982, is characterised by three main periods. The first one was fully dedicated to pioneer steps in Radiation Physics measurements, on-site audits and inventories of human resources, staff workload and department infrastructure in institutions participating to EORTC trials. During the second period, which started in the late 1980s, a series of quality systems were implemented to test the compliance of the investigators to follow protocol guidelines, through the use of standard and uniform control procedures like the dummy runs, in order to tackle systematic errors in the participating institutions. Finally, the third period, which took place in the 1990s, was essentially patient-oriented, thanks to large scale individual case reviews, to check the validity of data recording and reporting processes and trace random errors throughout the radiotherapy treatments. Most of the results collected during these two decades allowed the implementation of well codified quality control procedures which, nowadays, can be used outside the field of clinical research, by national societies or bodies willing to improve treatment standards on a large scale.

Keywords: Radiotherapy; Quality assurance; Disease outcome; Quality control

1. Introduction

Since 1982, the Quality Assurance (QA) Programme of the Radiotherapy Group of the European Organisation for Research and Therapy of Cancer (EORTC) was a continuous stepwise process from equipment calibration and dosimetric procedures to patient-oriented quality controls (a) to promote a systematic check of individual patients and (b) to improve the reliability of treatment procedures. Once general requirements needed to warrant a reliable cooperation were identified, the group directed its efforts to the clinical ground and in particular to validate control procedures improving the quality of phase III clinical studies. This general philosophy had a considerable impact in the writing of protocols, data management and detection and correction of dosimetric parameters as well. Most of these achievements were transferred to general radiotherapy practice outside of the EORTC and nowadays constitute standard references for delivering radiation therapy.

The QA Programme of the Radiotherapy Group was developed in three main periods based upon two Quality Systems: the Programme of Physics Audit Quality (PAQ) and that for Assurance of Protocol Compliance (APCP).

In the first period (1982–1987), most participating institutions were visited by a team of radiotherapists and radiation physicists. This was allowed by a grant of the programme 'Europe against Cancer' and later by a grant of the Flemish cancer league. This rather heavy and time-consuming step consisted of an inventory of radiotherapy, radiation physics equipment and human environment (inside and outside the radiotherapy department), extensive local equipment measurements (calibration procedures, beam quality, collimator and treatment tables controls). In addition, the pitfalls and complexity of multiple target volume dose distribution was demonstrated by the 'anatomical phantom head and neck radiotherapy intercomparison'. These pioneer steps established the methodology which remains today

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the basis of modern radiotherapy quality assurance. In 1987, a vast programme of mailed dosimetry was activated to detect, correct and update dose deviations between the values determined by the team of radiophysicists of the EORTC and those reported by institutions. The validity of this approach was documented by the disappearance of large deviations and the significant reduction of the other deviations observed during follow-up controls.

Mailed dosimetry replaced the local audits, allowed an increasing number of institutions to benefit of the QA programme and was the basis of protocol-oriented intercomparisons with *in-vivo* measurements.

In 1987, the Radiotherapy Group activated a second period of the QA programme, and set up a series of procedures (dummy runs) to document systematic errors made in single institutions and control the accuracy of the design and the application of phase III study protocols.

Finally, in 1989, a third phase, even more patient-oriented, was activated to tackle random errors: individual case reviews directed to patient data and treatment parameters were aimed at improving the compliance of the participating centers to study protocols and at detecting obscurities in protocol guidelines. The last decade was characterised by the further development of quality control procedures that had been validated during the three phases mentioned above with a particular emphasis put on the mailed TLD programme for the PAQ, and on dummyruns and individual case reviews for the APCP.

2. Baseline investigations on structures, human resources and methodology

2.1. Mailed in water dosimetry

This programme, which started in 1987, aims at performing mailed dosimetric audits and to periodically monitor absorbed doses at reference points for photon beams. Briefly, the given design criteria of this dosimetry system were ability to identify errors in values of absorbed dose larger than 3%. The dosimeters used are circular ships made of lithium fluor. The mailing procedure started with a questionnaire to the participating institutes, which were asked to provide the radiation physics reference centre, with information on beam qualities in use. Later on, they receive a mailing containing instructions for irradiation in water, data sheets, holders for in-water irradiation and a set of dosimeters. They are also instructed on how to perform irradiations. After irradiation, all the material is returned to the reference centre for read-out and absorbed doses determinations. To date, all participating centres have been monitored by mailed thermo-luminescent dosimetry (TLD), several more than once. The first time, this programme was run by the Radiation Physics Department of the Göteborg University Hospital. Since 1993, the mailed TLD programme has been handled by the Institut Gustave Roussy, in Villejuif. A collaboration is now in operation with ESTRO in the framework of the EQUAL Program. Nowadays, this programme allows beam output checks both on-axis and in complex setting.

The ratio between absorbed dose to water and that stated by the reference institute was used as a measure of agreement. Whereas in the early 1980s, the general conclusion of the TLD program was that less than 80% of the beams measured were within acceptable levels of variation for the absorbed dose stated, i.e. with deviations lower or equal to 4% [1], the main message of the current investigation is now that, with sequential mailings, an improvement of the basic dosimetry has been seen, as the mean ratio between EORTC determined versus institute stated doses progressively approached unity and standard deviations were decreasing. Of interest, it should be noted that, in some centres, the reasons for major deviations observed in radiation physics could be identified, corrected and checked by mailed dosimetry and through straightforward oral and written exchanges between visiting experts and either local radiotherapists or radiophysicists.

2.2. Questionnaire

A first questionnaire was activated in 1990. Since then, it has undergone constant updating. The aim of this questionnaire was to complete and update the information collected during various on-site visits carried out in the early 1980s regarding the equipment and human environment of all radiotherapy departments participating in the activities of the EORTC Radiotherapy Group. Indeed, some items had not been registered before, especially in the field of treatment techniques, biomedical and radiobiological environment. Thus the purpose of this questionnaire was: (a) to collect 'on time' data by sending a questionnaire to all centres entering patients in current protocols of the Group; (b) to specify the definitions of some items which had led in the past to difficulties of interpretation (for instance, workload and staff unbalance); and (c) to extend the questionnaire to items that had not been investigated before: brachytherapy, radiobiology, institutional quality control procedures, etc. Fifty centres answered the questionnaire. Equipment, human resources and workload are characterised by a very wide range of answers. Comparisons between data collected in the early 1980s and during a recent update show no difference in workload per megavoltage equipment and per simulator. The number of cancer patients treated per year, per radiotherapist and per member of the radiation physics team seems to diminish, especially for this

latter staff. The radiographer's workload showed an opposite trend. This survey also indicates that efforts have to be made in some institutions to reduce the workload at simulators. Moreover, in comparison with a previous report published in 1986, the present analysis undoubtedly emphasises an increasing use of CT-SCAN investigations in the treatment planning. The questionnaire now exists in an electronic and interactive version.

3. Quality control procedures specific to trials and patients

3.1. Dummy runs

Originally, the dummy runs were initiated to get impression of the planning facilities at the participating institutions. It was soon evident that the objectives of these procedures were not only to evaluate differences in treatment techniques and dose calculations but also to detect, within a few months after a clinical activation, the potential causes of poor compliance to the protocol and sources of heterogeneity in irradiations. Particular attention was also paid to the potential impact of treatment technique differences on heterogeneity of dose distribution. In the breast, heterogeneity might prevent investigators identifying clear-cut dose–control relationships. More specifically, in radiation physics, the main purpose of a dummy run is to evaluate differences in (a) treatment volume, (b) irradiation technique, (c) dose specification, (d) dose homogeneity and (e) uniformity of the dose to the specification point. In a dummy run, transversal slices of the relevant anatomic region are sent to the centres participating in the investigated clinical trial. Radiation oncologists and physicists are asked to design a target volume and to provide a treatment plan with dose distribution in each of these plans. They are also asked, as was the case for the dummy run for the prostate irradiation, to compute the absorbed doses in the points of interest indicated on the slices, both for dose prescription points and for those located in surrounding normal tissues. Finally, they were requested to complete a questionnaire on treatment technique and beam data. These dummy runs were carried out in the frame of three EORTC trials: trial 22881/10882 for breast cancer, trial 22862 for prostate carcinoma and trial 22931 for head and neck cancers.

3.2. Individual case reviews

This quality control procedure aims at improving the compliance of the centres to study protocols, with special attention to the minimal requirements of radiation physics experts and to the medical profiles and biomedical environments of radiotherapy departments. As in the dummy run procedure, another objective was to detect obscurities in the protocol of treatment in the very early phase of the trial. These reviews, carried out by a team of physicians and physicists, analysed the clinical and preclinical parameters contained in the charts of randomly selected cases. Since 1990, they have taken place before each Group meeting. Each time, four to five centres were asked to bring their clinical and technical charts to the expert team to discuss the several radiation physics and clinical parameters listed in the questionnaire. More specifically, the clinical data were reviewed with respect to eligibility criteria, documentation of tumour stage and staging procedures. Radiotherapy data were analysed for treatment technique factors, calculated dose levels and dose heterogeneity. Data were also compared with those forwarded to the Brussels Data Center. Finally, simulator films and gamma-graphies were compared.

The main problems identified by the dummy runs and the individual case reviews were related to uncertainties in target volume accuracy, heterogeneity of dose distribution, deviations in dose specification from protocol guidelines and protocol obscurities.

4. Conclusions

The goals of quality control procedures developed by the Radiotherapy Group are two-fold: firstly, through an improved quality of irradiation, to provide the highest possible accuracy of protocols studied on a multicentric scale; secondly, to provide all other radiation therapy centers with a methodology that has already been checked and confined through the 'test-bench' of trials conducted by cooperative groups. Throughout the last decade, the Cooperative Group for Radiotherapy has been able to extend its basic quality controls of equipment and dosimetry into prospective investigations consisting of pilot studies for systematic checking of individual treatment and treatment reliability, resulting in a large body of data on treatment precision level, systematic deviations and individual errors. The tackling of systematic and random errors has been extremely successful since the set up of control procedures such as the dummy runs and individual case reviews enabled the identification of the major sources of ambiguities as well as all causes of poor compliance to the protocols, resulting in the release of helpful recommendations for all participating centres.

Quality assurance programmes are not only well accepted by all participants but also felt by everyone to be a mandatory condition for the validity of cooperative work between several centres. This project is provoking lively and very constructive discussions within the Group, especially during the last 5 years where individual contacts among investigators and local teams

were boosted, for two reasons at least: firstly, this QA programme allowed harmonisation of treatments and provided clinicians with information on optimal workloads for equipment and human resources; secondly, this programme helps developing harmonised QC procedures in the therapeutic management of widespread diseases to improve, on a large scale, local control and survival, and reduce the severity of treatment complications. QA programmes should also be used as a first platform to the development of Quality Standards for electronic radiotherapy files. In the future, QA programmes in Radiotherapy should provide interactive novel tools as teleconferencing QA audits, remote data entry and monitoring to investigate the accuracy of both current radiotherapy treatments and new technologies.

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Further reading

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