RESEARCH STUDIES

Optimization of radio-therapeutic treatment and the program of quality assurance in ionizing radiation therapy

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Abstract

Background: The Program of Quality Assurance (PQA) in Ionizing Radiation Therapy (IRT) addresses the most important problems of assuring the quality of IRT utilization in the treatment of patients with neoplasm. In this context, the IRT value grows considerably, hence the implementation of PQA is of great significance. The study concentrates on a detailed description of the PQA as concerns the activity involving IRT devices applied in the IRT departments (rooms) of public medical/sanitary institutions, science research institutions etc., where IRT is employed using technogenic sources and ionizing radiation generators.

Material and methods: For the performing of the study, annual statistics reports about the activity of the IRT, and data of Cancer Registry of the Oncologic Institute of the Republic of Moldova were analyzed. The work also includes an in-depth description of the personnel categories involved in PQA, possible errors in radiotherapy, the responsibilities of the bioengineer in this program, importance of source calibration, the impact of the quality control in PQA, the role of topometric training, the interaction between the medical and technical personnel and the patient.

Conclusions: Optimization of IRT is very important and necessary in the Republic of Moldova. PQA incontestably contributes to reducing specialist's errors in planning correct treatment, dictates the need of team work and proper delegation of the responsibilities in co-optation of other professionals, performance of duty of bioengineering, the influence of quality control of profile installations, meaning accurate topographic planning, applying several methods of work, quality assurance program assuming the major importance.

Key words: quality assurance program, ionizing radiation therapy, cancer treatment.

Introduction

Currently, ionizing radiation therapy is successfully employed in the treatment of oncological diseases that occupy the second place in the Republic of Moldova in the ranking of the human disease morbidity. Cancer is a disease that arises from a direct impact of different noxious factors on the organism, including stress, smoking, irrational alimentation, defective genetics, ionizing radiations, chronic insufficiently treated diseases etc. All the above factors and asymptomatic or slightly pronounced cancer evolution at the initial stages contribute to its detection at tardy stages [3, 5]. In 2013, in the Republic of Moldova, 8,441 patients were diagnosed with cancer at various sites (8.204 in 2012), including rectal cancer (12.3%), breast cancer (11.8%), bronchopulmonary cancer (10.5%), bladder cancer (6.4%) etc. In 2012-2013, 5,734 and 5.835 cancer sufferers died, respectively [3]. The principal causes of cancer in the republic include excessive consumption of alcohol, smoking, obesity and sexually transmitted infections. Presently, 47.450 cancer patients are on file with the public medical/sanitary institution, the Institute of Oncology, which imposes a large scale employment of IRT [3, 5]. To improve the anticancer battle and, at the same time, to involve all the society segments: mass media, family etc. in it, medicine needs a substantial support. IRT must be implemented according to a program of quality assurance (PQA) in order to optimize the treatment of cancer located at different sites [6].

Material and methods

The article has been based on the analysis of annual statistical reports (F N30) regarding the activities of the IRT service in the Republic of Moldova, the report of the working group of WHO regarding assurance of quality in the area, specialized literature on the management of IRT assistance at the current stage in the republic and worldwide, and the Cancer Registry data of the Institute of Oncology. Background, documentary, and comparative and statistical analysis methods have been used.

Results and discussion

The IRT assistance must be currently provided in compliance with a QA Program depending on the departmental, national or international level. The principal responsibilities for the development and implementation of Q.A. Program are assigned to the head of the program that is, as a rule, the head of the IRT department. This person must be convinced that the ionizing radiation treatment meets the acceptable standards at the above levels.

One of the major problems of a PQA is to ascertain that a particular clinical or physical task has been accomplished. The head of the IRT department must insist that the results of the implementation of the tasks of quality assurance (QA) and calibration, data on the patients be registered correctly and retained for an appropriate period of time.

QAP dictates the necessity of a steadfast everyday team activity and correct delegation of the responsibilities to all the qualified specialists. The QA responsibilities of the IRT department personnel shall be distributed by the head who, based on their professional qualifications, delegates the clinical problems to oncologists/radiologists, while the technical ones to the bioengineer or engineers for maintenance of IRT devices. Taking into account the above and the complexity of the IRT application procedure, it is necessary to involve other categories of specialists who are in charge for treatment planning, dose calculation etc.

These categories are divided into some groups of specialists: medical profile specialist groups, a group of technical profile specialists and a group of diverse profile specialists (Quality Assurance in Radiotherapy, 1988, p.11, paragraphs 4, 5, 6, 7).

A. The group of medical profile specialists:

1. Oncologists/radiologists (OR) who are specialized in utilization of ionizing radiation for cancer treatment and are responsible for care of the patient, clinical definition of the target volume, monitoring of the patient during the treatment and dynamic supervision, and the results of the procedures conducted.

To successfully execute their activities, OR should be specialists with:

- sufficient familiariarity with all the possibilities of modern diagnostical methods of cancerous and nonspecific diseases;
- ample knowledge in the therapeutic possibilities and the limitations of surgery, chemotherapy, hormone therapy etc. to make decisions about utilization of a method when IRT is the most helpful curative agent;
- solid training in utilization of ionizing radiation to treat cancerous and nonspecific diseases;
- extra training of at least 3-4 years for perfection and acquiring experience at a prestigious oncological institution following the graduation of the medical department, specialized in all the oncological aspects of ionizing radiation biology, dosimetry, radioprotection and radiation safety;
- competence in imagistic diagnosis techniques, sufficient experience of general practitioner, and patient care skills in the conditions of an in-patient unit;
- an appropriate certificate issued by a national authority and a full-time employment as an oncologist/radiologist;
- possibilities of continuous education during the activities in the area (lack of serious health problems, fear of traveling by the modern transportation means, traveling on altitudes etc.) [6, 8].

2. Radiology or medical technicians are specialists with medium medical education followed by a course of at least two years of training in IRT technology. The course must include both studying human anatomy, physiology and pathology including oncological diseases, and radiation physics, radiobiology, radioprotection, radiation safety, IRT planning, patient care etc. (6, 8 – Quality Assurance in Radiotherapy, 1988, p.11, paragraphs 7, 8).

These specialists are responsible for:

- correct positioning of the patient, wedge filters, radiation blocks etc.;
- execution of routine radiation of the patient, including IRT using set-up devices;
- data records 6, 8).

3. Physiotherapist and occupational therapist who help the patient to resume everyday activities;

4. Psychologist who helps the patient overcomes the emotional effects of cancer and its treatment [4].

B. The group of technical profile specialists:

1. Physicists, specialists in medical radiation, bioengineers and dosimetrists responsible for the physical aspects of radiation techniques, treatment planning, dosimetry, radioprotection, radiation safety etc. These specialists must be trained in medical applications of ionizing radiation and be knowledgeable in radiation physics, including radiation generation, dosimetry in treatment planning, radioprotection, and in human anatomy and physiology, radiobiology and oncolology.

The above specialists must hold a university or equivalent degree in the area of physics, specifically in radiation physics, be experienced in IRT utilization and skills in dealing with patients. The education should be of three years and certification must be earned [6, 8].

These categories of the persons are responsible within QAP for:

- radiation dosimetry;
- physical aspects of IRT planning;
- radioprotection of the patients and medical personnel;
- design and construction of equipment: beams and devices with limiting beams;
- quality assurance surveillance in IRT;
- consulting in selecting IRT equipment;
- radioprotection and design of adequate facilities.

The bioengineer (medical physicist) is in full charge of the physical and technical aspects of PQA though some less sophisticated verification may be conducted by radiology technicians or dosimetrists subordinated to him/her.

2. Engineers (bioengineers) that must have a high level technical education with an additional training in IRT equipment. The training consists in the initial education provided by the producer followed by continuous professional training (advanced training).

Engineers (bioengineers) are responsible for:

- correct technical maintenance of IRT units, dosimetric equipment etc.;
- resolving technical issues associated with mechanical or electronical flaws, all the aspects of ionizing radiation;
- drafting, together with the rest of the personnel, of the IRT program.

C. The group of different profile specialists:

1. Dietician/nutritionist who recommends the best plan of alimentation during the treatment and recovery;

2. Speech therapist for assessment and treatment of any adverse reaction that might affect the speech and swallowing.

The Department QA program shall include the following responsibilities: program establishment, including the as-

pects of database, check on the patients' doses, patient and personnel safety.

At the same time, no possible errors can be singled out in the patients' treatment that may be committed for the following reasons [4, 6]:

a) incorrect definition of the patient's anatomy: inexact completion of the sketch, incorrect positioning of the patient, incorrect appreciation of the organs at risk, erroneous estimation of tissue homogeneity etc.

b) inexact appreciation of the target volume: shape, sizes and localization, denial of the influence of the physiological motions of organs and tissues (the influence of blood circulation, respiration, unintentional motions of the patient etc.);

c) incorrect treatment planning: errors in the beam characterization, beam models, software and hardware etc.);

d) incorrect implementation of the treatment with an inaccurate calibration of the unit;

e) inexact appreciation (confusion) of the patient: incorrect identification, incorrect diagnosis, erroneous application of the medical treatment prescription and of the previous treatment results etc.

An important role in QA in the IRT activity is attributed to the bioengineer who is obliged to:

- calibrate and technically adjust IRT devices according to the duly approved treatment programs;
- participate in the checks on the qualitative operation of the IRT devices;
- assure momentary detection of the work stoppage of any segment of ionizing radiation sources and considerable diminution or complete exclusion of unplanned exposure to ionizing radiation of the patients under treatment and the personnel of the IRT service;
- contribute to reduction of the level of exposure to ionizing radiation of the patients through assuring a higher quality of IRT;
- correctly calculate the radiation plan for the patient so that the necessary therapeutic effect be achieved through application of minimal but efficient radiation doses, protection or effective shielding of patient's healthy organs and tissues;
- participate in the permanent medical personnel training in the issues of radioprotection and source safety pursuant to the laws [6, 7].

Source calibration is the prerogative of the bioengineer who must:

- assure calibration of devices and equipment of the IRT service according to the radiation energy and quality and in the units of the dose absorbed or the debit of the dose absorbed, at a distance set earlier, in specific conditions and in compliance with Directive 97/43/Euroatom dated 06.30.1997 [2];
- conduct calibration of the closed sources for brachytherapy after the activity, the control debit of the Kerma index or of the source of the dose absorbed for an environment after a certain time fixed and at a distance determined from the source with indicating the calibration date;
- calibrate radiation sources prior to starting exploitation, following each repairs (in the case of impact upon dosimetry) and in the intervals determined by the hierarchically superior bodies;
- permanently improve knowledge to be a specialist accredited to calibrate the above sources in compliance with the laws.

Within IRT, the bioengineer must ensure estimation and enactment of the following volumes of:

- minimal and maximal doses absorbed in the planned radiation volume, radiation dose prescribed by the physician, in the point of destination and of the dose absorbed in other points determined by the physician during telegammatherapeutic procedures;
- the doses absorbed for particular organs;
- the dose absorbed in particular points of the patient's body in the case of brachytherapy.

The bioengineer assures an optimal exploitation of the devices (equipment) so that the planned target volume designed for radiation receive the prescribed absorbed dose according to the time and energy indicated, while the radiation dose for other organs be minimal [4, 6, 7, 8].

QA of the exposure to ionizing radiation is a very important area in the profile activity, vital in meeting radioprotection and source safety [7]. In this context, the bioengineer must efficiently participate in the development and implementation of the QA program in the exposure to ionizing radiation.

The QA program in the exposure to ionizing radiation includes the following management measures:

- the order of physical parameter evaluation for radiation devices;
- verification of appropriate physical factors employed within implementation of the radiotherapeutic treatment;
- control of the quality (CQ) and the exploitation conditions of dosimetric and monitoring equipment;
- systematic and high-quality verification, together with independent experts, of the order of the QA program implementation of treatment procedures.

QA programs regarding medical exposure within IRT application are directly influenced by the implementation, at the due level, of the CQ of the IRT equipment. This control is conducted at the acquisition and installation of the device with the assessment of its performances. The control is conducted periodically following repairs concerning [1]:

- mechanical, electrical, and radiological safety;
- mechanical and geometrical characteristics;
- dosimetric characteristics of the beams.

The mechanical and electrical safety is assured through the following verification frequency:

- display of functioning parameters – daily;
- motion command – daily;
- entrance door – daily;
- emergency radiation shutdown – daily;
- shutdown following treatment termination – monthly;
- table shift – monthly;
- scaling – quarterly.

Radiological safety:
- audio-video system – daily;
- beam command – daily;
- monitor – monthly;
- patient and personnel protection – annually.

Mechanical and geometrical characteristics:
- telemeter for all distances: ± 0.2 mm, weekly and after interventions;
- rotation of the bracket support of the radiogenic head in the principal positions for horizontal and vertical beams; tolerance ± 0.5 – monthly;
- head rotation on the support in reference and scaling position 0 ± 0.2 mm – monthly;
- isocenter: ± 0.2 mm – monthly;
- centerer: the point of the beam axis entrance to the collimator axis ± 0.2 mm – monthly;
- light field that includes the following parameters:
  - coincidence of the light field with radiation field, densitometric comparison with radiation fields, ± 0.2 mm – monthly and after interventions;
  - correspondence with the display indicating light field dimension;
  - coincidence of opposite fields.
- collimator rotation: ± 0.5 – monthly;
- collimator symmetry and parallelism: ± 0.2 mm, monthly;
- penumbra – monthly [1].

Prior to starting the treatment, all the information delivered to the patient by the attending physician is recorded in the treatment consent that is signed in two copies, one for the patient and the other is attached to the medical chart. The attending physician will actively follow the medical evolution of the patient during the whole treatment period and will complete, at each consult, a monitoring sheet indicating additional investigations that the patient will have to perform during and after the treatment [4, 6].

After the treatment plan has been developed, it is verified through virtual simulation, and final coordinates of the tumor volume are determined, which is indispensable for IRT application. The simulation includes patient's positioning on the table CT SIM and fixation of the three real Cartesian system coordinates of the numbers that define the patient's position in relation to two or three axes perpendicular to each other. These coordinates are fixed with special markers [4].

After the completion of the virtual simulation, the patient is accompanied to the IRT device, initially being instructed on his/her behavior in the treatment room. The radiological technician carefully verifies the patient's identity (in this regard it is desirable to attach a recently taken photograph of the patient in the clinical observation sheet to avoid his/her confusion with another patient and rule out possible human errors). Further, the radiological technician selects the treatment plan established by special software and sets, if necessary, the positioning systems on the treatment table inviting the patient into the procedure room. The patient positioning is accomplished in a strict compliance with the indications from the treatment plan and is verified through utilization of a laser system obligatorily identical to that applied at virtual simulation at CT SIM [4, 6].

During the treatment, the patient is monitored by the radiological technician with the help of an intercom and a camera through which they communicate with each other (the both systems must be functional). The correct positioning of the patient is of a paramount significance in order to obtain the expected results and, therefore, requires supplemental verification with the aid of imagistic techniques, which is carried out for the positioning and check on the treatment plan coordinates, digital radiographies to the radiography system that must be a part of the linear accelerator.

The positioning verification is accomplished at particular IRT sessions. In this context, the time the patient stays in the procedure room will range from 2-3 minutes to 10-15 minutes (sometimes more) in the case of the sessions where the patient's positioning is verified and digital radiographies are performed. It is recommended to hold the first IRT sessions in the afternoon when the positioning on the treatment table is verified according to a well-established procedure with the participation of the bioengineer. The time of IRT sessions should be observed as much as possible in terms of radiobiological aspect without changing the IRT team as they are already familiar with the specificity of each patient and may inform promptly the IRT attending physician on possible modifications during the treatment.

A correct radiation of the patients with malignant neoplasm is possible only if the following principles of the clinical topometry are observed [6]:
- establishment of the level of "copying" of the body contour above the projection of the tumor center and decoupling of the contour itself;
- accomplishment of special investigations and other examinations to determine the shape and actual sizes of the pathological source, its topographic location, lymph circulation pathways, particular features of syntopy with adjacent organs, the depth of the location in the patient's body;
- drafting of the anatomotopographic schemes of the body transversal section at the level of the maximal tumor size;
- marking of the tumor projection on the patient's skin, formation of radiation fields, and determination of the radiation beam centering;
- verification of the planning correctness and reproduction of radiation conditions [6].

Simultaneously, the topometric preparation of the patient includes the following measures, as well:

1. Strict individualization for each patient in his/her topometric preparation.

2. Strict examination of the patient in the position that will be applied during the treatment.

3. Maximal approach of the physiological condition of the patient during examination to the physiological condition during IRT application (time intervals between meals, acts of defecation and urination, depth of breathing). All these

measures are meant to assure an equal degree of the cavitary organ filling and the physiological condition of the organism.

4. Combination of the maximal possibility of the examination precision with assurance of minimal discomfort for the patient and milder conditions of the IRT application by the personnel. Most frequently, this refers to accomplishment of radiodiagnostic investigations, early implementation of angiography, lymphography, scintigraphy, computer tomography, magnetic resonance imaging, positron emission tomography etc.

Conclusion

1. The Program of Quality Assurance contributes decidedly to reduction of the error number in the correct treatment planning.

2. This Program dictates the necessity of the permanent daily team activity and correct delegation of the responsibilities to all the qualified specialists.

3. In order to obtain a beneficial result for the patient, it is currently necessary to recruit a dietician/nutritionist, speech therapist, physiotherapist, occupational therapist, and psychologist along with the specialists incorporated into PQA up to now.

4. Simultaneously with the medical personnel of the institution, a major responsibility in the PQA rests on the bioengineer/engineer who is responsible for the maintenance of IRT devices, correct drafting of the radiation treatment etc.

5. The program of quality assurance of IRT is directly influenced by the implementation of the quality control of the profile equipment at an appropriate level.

6. Enhanced efficiency of IRT may be assured by a correct topometric planning for the patient, adequate behavior of the medical and technical personnel towards the patient etc.

7. Optimization of the treatment with ionizing radiation may be obtained through multiple activity modalities incorporated into the QA program recurring its major importance.

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