

7 Cancer radiotherapy: a justified practice but one that demands considerable stringency on the part of the operators and vigilant supervision by ASN

As part of its regulatory duties, ASN attaches particular importance to the radiation protection of patients, especially during the course of radiotherapy, in which the highest doses are delivered, with potentially serious side-effects.

Accidents and incidents in France

In 2005 and 2006, 4 serious radiotherapy accidents were declared by various hospitals in France:

- a software malfunction led to serious over-exposure of a patient in Grenoble, requiring remedial surgery;
- an error in the size of the irradiation field led to the death of a patient in Lyon;
- incorrect use of a software was directly responsible for over-irradiation of 23 patients in Epinal, one of whom died and several of whom still carry serious burns;
- over-exposure of a patient in Tours as a result of abnormal and unplanned overlapping of irradiation fields.

4 other incidents, with unknown health consequences to date, were also declared:

- patient identification errors on 21 August 2006 and 19 October 2006 in Angers;
- erroneous irradiation of a patient on 28 June 2006, during a radiotherapy session in Saint-Etienne;
- on 2 June 2006, an iridium 192 source was implanted in a brachytherapy patient at the Amiens university hospital and then forgotten;
- incidental exposure of a brachytherapy patient, following incorrect positioning of a radioactive source and malfunctioning of the source projector used in Tarbes.

These accident declarations by hospitals are the result of both the patient information requirements contained in the law of 4 March 2002 on patient rights and the quality of health provision and ASN requirement for declaration of incidents pursuant to article L1333-3 of the Public Health Code.

Each declared event provides feedback which should help improve the quality and safety of radiotherapy. One must therefore applaud the responsible attitude of the radiotherapists who have agreed to join in this move towards trans-

parency by declaring events that have occurred to their patients. The declaration of incidents/accidents by the profession is indicative of the positive change in cultural attitudes to radiation protection in France.

How do these accidents happen?

How can an accident happen if the:

- radiotherapist has chosen the volume to be irradiated and has taken care to spare the surrounding sound tissues;
- three-dimensional dosimetry calculations determine the dose distributed to the tumour and the surrounding organs;
- beam ballistics and beam collimation define the irradiated volume while masking areas at risk;
- dose calculations are verified;
- irradiated areas are checked once a week - during irradiation by a real-time imaging system;
- patient is positioned by two operators, and if the patient is regularly examined by the radiotherapist?

The systematic investigations of these events carried out by ASN have showed that their origins are to a very large extent attributable to organisational and human shortcomings. In one example, a widely used software package was employed in a new configuration which had not been completely tested. In a second case, there was an error in a spoken instruction concerning the size of a field, with the values being understood in mm by one operator and in cm by another. In a third case, the treatment parameters were set differently between the planning stage and the actual operation, leading to overdosing of sound tissue.

It should also be noted that most radiotherapy departments in France are under-staffed. In some departments therefore, radiotherapy is carried out by personnel who are overworked. An investigation is under way to estimate the medical physics needs in order to identify those radiotherapy departments which require extra staff in order to improve treatment safety.

ASN actions

Following the Grenoble accident, ASN in April 2005 issued a reminder to radiotherapists of the



Filter used for radiotherapy

principles of the regulations to radiotherapists in order to increase compliance, thereby helping to ensure the safe use of radiotherapy. After the Lyon accident in April 2006, ASN issued to radiotherapy professionals a new circular to increase their awareness of the organisational and human factors that contribute preventing radiotherapy accidents.

Since the Epinal accident, ASN has strengthened this approach and:

- asked all radiotherapy professionals and the National Cancer Institute (INCa) to present what steps they intend to take to fully incorporate the organisational and human factors aspect into how they run their departments;
- sent radiotherapy professionals, for application, a draft guide on declaration to ASN of all radiotherapy events, even those with no health consequences. ASN stressed the importance of ensuring that declarations are made without delay so that feedback may be rapidly obtained and that persons concerned can be given appropriate medical care and attention.

ASN has also begun to learn all the lessons from the declared incidents/accidents and in particular the Epinal accident as part of the duties entrusted to it jointly with the General Inspectorate of Social Affairs (IGAS) by the Ministry for Health and Solidarity on 12 October 2006.

Finally, ASN and the National Cancer Institute have asked the French oncological radiotherapy society (SFRO) to draft a tumour radiotherapy guide dealing with external irradiation techniques and quality criteria. This guide was completed at the end of 2006 and now constitutes a national reference work. The ASN expects this guide to be applied by all radiotherapy professionals.

Outlook

Radiotherapy is a beneficial practice in the treatment of cancers and is used every year to treat 180,000 of the 280,000 people who develop cancer. Furthermore, as its financial impact is moderate (about 8% of the cost of combating the cancer) radiotherapy will no doubt develop further. But it is not completely risk-free, even if the incidence of risk is relatively low when we con-

sider the number of patients treated. The following factors also have to be taken into account:

- the ageing of the French population is leading to a significant rise in the number of cancers to be treated;
- the shortage of professionals (radiotherapists, physicians and operators) in our country, meaning that some teams work at full-stretch, will not be rapidly remedied;
- the increasingly complex irradiation procedures are placing greater demands in terms of personnel training.

The necessary efforts must therefore be made to reinforce the safety of radiotherapy treatment within the framework of the Cancer Plan. ASN will thus be expanding its supervision to cover organisational and human factors. Its inspections will assess the measures taken and ASN will in particular check that each department implement a register of events, reviews them periodically and learn from these reviews for the future.

The practice of radiotherapy

A justified practice

Radiotherapy was first developed in the 20th century and, along with surgery and chemotherapy, is one of the 3 leading forms of cancer treatment. Cancers are serious diseases affecting about 25% of the population. About 280,000 new cases of cancer are diagnosed every year in France. Radiotherapy is proposed as treatment for half, and cures 80% of them.

Radiotherapy is thus among the major treatments mentioned by the Cancer Plan presented by the President of the Republic in July 2002. This plan, which is under the control of the National Cancer Institute (INCa), has allowed the modernisation of radiotherapy in France: installation of new equipment, in particular linear accelerators, access to innovative techniques (brachytherapy of the prostate, tomotherapy, stereotaxic radiotherapy, accelerators on robot arms).

Radiotherapy is carried out by qualified personnel: radiotherapist oncologists, hospital physicians and electroradiology operators, forming a true medical care team.

The choice of radiotherapy

The decision to use radiotherapy for a particular patient is made at a cross-disciplinary meeting involving various specialists; clinicians, surgeons, radiotherapists, chemotherapists. A personalised care programme is drawn up and proposed to each patient, who is informed of the nature of his or her cancer, the irradiation technique used and its side-effects.

The radiotherapist and the medical physicist draw up the treatment plan, based on the scanner image plus, if necessary, magnetic resonance imaging (MRI) or positron emission tomography (PET), to target the tumour in 3 dimensions. The physical treatment parameters are transmitted to the radiation emitting device via a parameter recording and validation system which means that irradiation can only be triggered if the actual and planned parameters coincide.

The treatment prescribed by the physician is carried out daily by the operators (who are informed of the patient's file) 5 days a week for 6 to 7 weeks. The patient is precisely installed in a reproducible position under the treatment apparatus and the operators trigger irradiation in accordance with the parameters decided on when drawing up the treatment plan. The appliances are regularly maintained by the manufacturers and quality control procedures are carried out by medical physicists to check the validity of the appliance characteristics and the quality of the beams produced.

Side-effects

If it is to be effective, cancer treatment requires the use of powerful techniques. With regard to radiotherapy, the paradigm is as follows: deliver the highest possible dose of ionising radiation to the tumour, while irradiating the surrounding sound tissue as little as possible.

Radiotherapy also relies on the particular capacity of sound cells to recover more readily than cancerous cells from a radiation dose of about 2 Gy. Therefore each radiotherapy treatment is split up into about thirty daily sessions.

The effectiveness of radiotherapy in the end depends on the correct dosage of the radiation delivered: an insufficient dose will not cure, while an excessive dose could have side-effects on the surrounding tissues, especially burns. These side-effects can be observed, sometimes belatedly and even if there is no error in the radiotherapy procedures, in about 5% of cases. They are in particular due to individual susceptibility to radiation, stemming from a lesser ability to repair the DNA lesions created by the radiation.