PATIENT SAFETY

PAVING THE WAY FOR PROGRESS

#

June 2020

PRIOR RADIOTHERAPY TREATMENTS

Newsletter for radiotherapy professionals

asn AUTORITÉ DE SÛRETÉ NUCLÉAIRE | sfpm | afppe ASSOCIATION FRANÇAISE DU PERSONNEL PARAMÉDICAL D'ÉLECTRORADIOLOGIE | AFQSR | sfro Société Française de Radiothérapie Oncologique

EDITORIAL

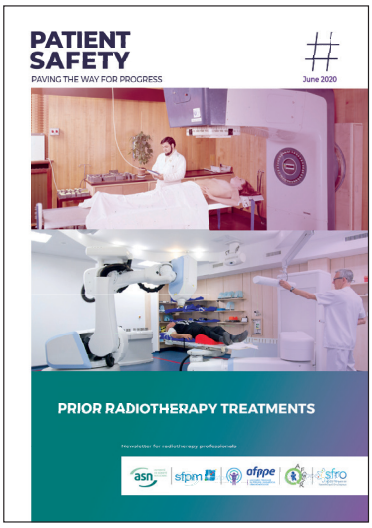
More and more patients receive several radiotherapy treatments in the course of their lifetime, following a relapse, a second cancer or an extension of the disease. This is made possible thanks to technical innovations and improved precision and efficacy of the radiotherapy treatment.
Re-irradiations necessitate the management of treatment intervals that can range from a few weeks to several decades. This represents a new clinical issue for which ASN has observed events that sometimes have serious consequences for the patient.

It is sometimes difficult, if not impossible, to identify and take into account a patient's radiotherapy treatment history, depending on how far back the previous treatment dates and the centre in which it was carried out.
The multidisciplinary working group has decided, in this newsletter, to draw the attention of radiotherapy professionals to this emerging problem.

In this newsletter issue, the Gustave Roussy Institute (Val de Marne département) and the Charlebourg Oncology Centre (Hauts-de-Seine département) share their good practices in the management of patients with a radiotherapy treatment history. The working group's recommendations underline the double challenge of anticipating the reirradiations and taking into account the radiotherapy treatment history to avoid the unwanted treatment of previously irradiated anatomical regions.

We wish you enjoyable reading!

The Editorial Team



CONTENTS

PATIENT SAFETY - Paving the way for progress is published by the French Nuclear Safety Authority (ASN) as part of the work of the multidisciplinary working group specially created to provide radiotherapy professionals with feedback.

- **Publications Director:** Olivier Gupta, Director-General of ASN
- **Chief Editor:** Nathalie Clipet
- **Author:** Patrice Roch
- **Editorial Committee:** French Radiation Oncology Society (SFRO), French Society of Medical Physics (SFPM), French Association of Radiographers (AFPPE), French Association of Quality and Safety in Radiotherapy (AFQSR).
- **With the participation of:** IRSN (French Institute for Radiation Protection and Nuclear Safety), ANSM (French Health Products Safety Agency) and HAS (French National Authority for Health).
- **Photo credits:** Archives AP-HP, 31FI357; Marie-Laure Luca –Léon Bérard Centre
- **Design and production:** quatrebis.fr

SUBSCRIBE

To receive the PATIENT SAFETY newsletter, create your account on: https://www.asn.fr/connexion

Key figures

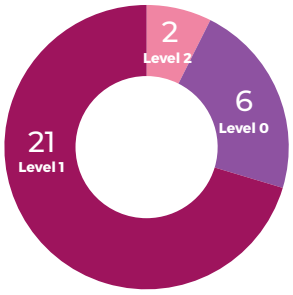
Between June 2009 and June 2020, 29 significant radiation protection events (ESR) involving patients with a radiotherapy history were reported to ASN.

Ten of these ESRs resulted from failure to take into account, or incorrect taking into account, of a previous irradiation. In the 19 other cases, the cutaneous landmarks of a previous treatment led to delivery of the radiotherapy with incorrect positioning.

BREAKDOWN OF ESR'S ACCORDING TO THE NUMBER OF SESSIONS INVOLVED:

- 24 Single session
- 2 More than half of the planned sessions
- 3 The entire treatment

CLASSIFICATION ON THE ASN-SFRO SCALE:



Benchmarks

WHAT ARE THE ISSUES CONCERNING PRIOR RADIOTHERAPY TREATMENTS?

Current radiotherapy techniques under stereotactic conditions or with "high-precision" intensity modulation provide the possibility of re-irradiating patients on previously treated anatomical regions or adjacent regions.

In these situations the treatment must be prepared such that the radiation dose delivered does not sum with the previously dose and produce deleterious effects.

The aim is to minimise insofar as possible the clinical risk associated with a prior treatment.

WHAT ARE THE REGULATORY REQUIREMENTS CONCERNING THE RETENTION OF MEDICAL DATA?

The Public Health Code (Articles R. 1112-2 and R. 1112-3) indicates the content of the medical file to be established for any patient hospitalised in a public or private healthcare facility, but does not specifically address radiotherapy.

Article R. 1112-7 sets out the retention rules for patients' medical files: twenty years counting from the date of the patient's last hospital stay or last outpatient consultation; ten years counting from the date of death, if applicable; in paediatrics, until the 28th birthday of the patient.

WHAT FUNCTIONS DO MANUFACTURERS PROVIDE TO CONSERVE THE HISTORY OF THE PATIENT'S CARE PATHWAY?

Radiotherapy information systems (RIS) allow the care pathway of each patient to be organised, tracked and safeguarded, from treatment prescription to delivery, but do not integrate the notion of prior treatment history and do not interconnect with all types of treatment devices.

Given the increase in reirradiation frequency, an improvement in the tracking aids and connectivity between systems is becoming absolutely essential, particularly for the high-precision techniques.

Decoding

COMPLEXITY AND HETEROGENEITY OF RE-IRRADIATION SITUATIONS

It is difficult to identify and take into account prior radiotherapy treatments due to the numerous factors in play:

- location of the treatment to deliver: identical/ contiguous (relapse) or distant from the previous irradiation (second cancer, metastases);
- time elapsed between the two treatments: from a few weeks to tens of years;
- place in which the initial treatment was carried out: another facility that have closed down or been reorganised;
- device and technique used for the previous treatment: contemporary with the reirradiation or outdated, such as cobalt therapy;
- complexity of the technique: 2D, 3D conformal radiotherapy, intensity-modulated, etc.
- radiobiological aspects: type of organ concerned and tolerance to the previous treatment.

PRACTICAL DIFFICULTIES ASSOCIATED WITH THE RADIOTHERAPY TREATMENT HISTORY

Access to the prior treatment history:

- sometimes the patient is the only person who knows;
- the patient may not remember or may not be able to make the link between the various terms used in a radiotherapy treatment.

Availability of technical information concerning the previous treatment:

- the previous file was established in another healthcare facility: geographical separation, transfer difficulties, closure of the service, loss of data (flood, fire), private practice (each practitioner is responsible for archiving their files);
- time taken to retrieve file from the archives and transfer it if archived on a different site.

Usability of the previous technical data:

- if the treatment dates back a long time: the dosimetry and imaging may be inexistent, the beams not modelled in the TPS (Treatment Planning System) (cobalt-60), etc.;
- the data are archived on media that cannot be used (magnetic tapes, DAT cassettes, CD, etc.);
- 2D and 3D conformal techniques can be "reconstituted" from simple data (paper) whereas intensity modulation techniques imply having digital dose distribution data (DICOM RT_Dose files) that are compatible with software of the centre.

IDENTIFIED CONSTITUENT CAUSES AND FACTORS

The ESRs associated with a previous irradiation occurred during two crucial steps of the radiotherapy treatment:

During treatment preparation:

- poor knowledge of the radiotherapy treatment history;
- previous technical file not available (non-existent or not sent);
- treatment started before receiving the previous treatment file;
- under-estimation of an irradiation field overlap (omission or poor assessment of risk).

When delivering the treatment:

- patient centring errors due to confusion between the old and the new radiotherapy tattoo marks.

Steps for progress

Good practices - Recommendations

Any patient undergoing radiotherapy treatment may receive another treatment in the short, medium or long term. Consideration of the irradiation history must be included in the prospective risk analysis, be based on a formalised process and be shared by the entire healthcare team.

ANTICIPATE THE RE-IRRADIATIONS

- Optimise the treatment plans taking into consideration a possible future reirradiation (lowest reasonably achievable dose to the organs at risk).
- Establish a complete technical file for each patient that is usable over a long time frame to define a potential future treatment, including in another centre.
- Adopt an archiving format that is as long-lasting as possible:
  - retain the data for a target duration of 20 to 30 years, longer than the term required by the regulations;
  - store the data separately from the TPS, which is subject to regular changes of technology and machines;

- use in priority the DICOM and DICOM_RT formats (image, structure, dose, plan), which provide the possibility of dosimetric summing of the previous treatment plans with the envisaged plan;
- if the treatment dates back too far, prefer paper format to CD or DVD media, which are less stable over time, and plan for double archiving on a separate medium from that of the manufacturers.

DETECT THE IRRADIATION HISTORY

- Include the questioning about a previous irradiation at the multidisciplinary consultation meeting;
- Question the patient about his/her treatment history during the first consultation with the radiation oncologist and with the paramedical team;
- Establish a matrix of key words to record elements of the medical history that the patient does not necessarily naturally identify as relating to radiotherapy: "rays", "cobalt", names of machines, etc. ;
- Be particularly vigilant when the patient is new to the centre (married name, compound surnames, etc.);
- Plan for irradiation history detection points at the key steps of the treatment (CT scanner checklist and contouring, questioning by the radiographer).

When a prior radiation history has been identified:

- refer the patient back to the original centre for the new radiotherapy treatment or, failing this, retrieve the previous treatment data;
- clearly differentiate the radiotherapy tattoo points of the previous and current treatments.

ASSESS THE POTENTIAL RISKS OF THE NEW TREATMENT

The radiation oncologist will adapt the proposed treatment to the risks of secondary effects potentially caused by the radiotherapy treatment, according to the clinical context.

The justification for taking irradiation history into consideration is based on several factors:

- is the treatment a curative or palliative treatment? In a palliative treatment situation, the patient's survival prognosis should lead to consideration of the likelihood of potential latent effects resulting from the accumulated radiation set off against the expected therapeutic benefits (medullar decompression, haemostasis, analgesia, etc.).
- is reirradiation clinically appropriate?
- does the envisaged treatment concern a previously irradiated region?
- is"overlapping" possible? Certain?
- which organ(s) is (are) concerned? Serial organ, critical organ (brain stem, chiasm, marrow, etc.) ...
- is the delivered dose therapeutically relevant?

TAKE THE PREVIOUS TREATMENT INTO ACCOUNT: PRACTICAL ASPECTS

From the moment there is justification for taking the radiotherapy history into account, the aim of the medical professionals shall be to dosimetrically quantify the impact of the accumulation of the old and the new treatment on the control of the tumour and the toxicity for the healthy tissues.

Depending on the situation – reirradiation at a close or distant interval, in the same medical centre or not – the method and uncertainties can vary greatly and depend on the answers to the following questions:

- how far back does the previous treatment date?
- is the technical file for the previous irradiation available and usable?
- does the service have the necessary tools and data for the dosimetric study and the summing of the treatments? The previous treatment plans must be available before the volumes concerned by the new treatment are contoured.
- what are the uncertainties on the dosimetric result obtained?

CONTENT OF A COMPLETE RADIOTHERAPY FILE:

- **medical information:** history of the patient and his/her illness, prescription and monitoring;
- **preparation imaging examinations:** CT scanner and other methods if applicable (MRI, PET-CT);
- **structure data resulting from the contouring:** target volume (s), organs at risk, optimisation volumes, margins applied to the different structures;
- **ballistic data:** geometric (angles) dosimetric (intensity) description of the irradiation beams and fields;
- **"dose" data** used to view or recalculate the dose distributions and dose-volume histograms.

Other useful information, excluding parameters used in the reirradiation dose calculation:

- control images;
- results of "patient" quality controls;
- *in vivo* dosimetry results.

When an irradiation history has been identified, digitise and integrate in the file all the data concerning the preceding irradiations.

The experience of the centres

Doctor Pierre BLANCHARD, practising at the Gustave Roussy Institute, treats both his own patients and those referred to him by centres that do not have the technical capacity or experience necessary to treat them.
Professor Jean-Marc COSSET, a radiation oncologist since the 1970's and currently at the Charlebourg Cancerology Centre, frequently has to initiate new radiotherapy treatments in the long-term monitoring up of his patients.

"Some severe or even fatal complications must be put into perspective with the quality of life and life expectancy of the patients if the treatment is not carried out"

Doctor Pierre BLANCHARD
Radiation oncologist
at the Gustave Roussy Institute, Villejuif

"«Time-Dose Factor» remains a radiobiologically debatable notion"

Professor Jean-Marc COSSET
Radiation oncologist
Charlebourg Cancerology Centre (Amethyst Group), La Garenne Colombes

■ In what circumstances are you faced with reirradiation situations? Is this becoming a more frequent issue?

P. BLANCHARD - Gustave Roussy has extensive experience in reirradiation, particularly with head and neck cancers, which have been the subject of several clinical tests. In a palliative situation, a given patient is sometimes treated 2, 3 or 4 times, perhaps more, for secondary cancers. In our centre, reirradiations represent a few hundred patients out of about 4,500 radiotherapy treatments per year. There does not seem to be a significant increase in situations requiring a new radiotherapy treatment. Nevertheless, the technical progress made over the last few decades have increased treatment precision, which makes it possible to prescribe reirradiation, including at "full" doses, in situations where in the past the potential toxicity of the second treatment would have ruled it out.

JM. COSSET - There are effectively clinical situations where current techniques make reirradiation possible, whereas previously it could not be envisaged. This is the case in particular with prostate cancers, which can be re-treated by brachytherapy with permanent implants following external beam radiotherapy.

Aside from failures of a previous radiation treatment, it might be necessary to treat secondary cancers or radiation-induced cancers that occur years after an earlier radiotherapy treatment.

■ How do you assess the benefit/risk trade-off when considering a second radiotherapy treatment?

P. BLANCHARD - Reirradiation represents a significant risk, higher than that of an initial treatment. Some severe or even fatal complications, such as rupture of the internal carotid artery (30% risk in reirradiation of the nasopharynx) or urethro-rectal fistulas (in prostate reirradiations) must be put into perspective with the quality of life and life expectancy of patients if the treatment is not carried out. The patient is informed of the risks and expected benefits and has his/her say in the final decision of whether to reirradiate or not.

JM. COSSET - We take into account all the dosimetric data available from the previous radiotherapy treatment along with the current technical possibilities when assessing the risk. The therapeutic decision also takes account of the individual radiosensitivity of the patient: poor tolerance to the first radiotherapy treatment requires a cautious approach and may give grounds for excluding reirradiation.

■ How do you take the previous doses and volumes into account? Do you apply a "Time-Dose Factor"?

P. BLANCHARD - At present there is no benchmark or professional recommendations concerning the consideration of a "Time-Dose Factor". Nevertheless, the maximum doses delivered to the organs at risk are conservative, in accordance with the professional recommendations such as Recorad. For example, the commonly

accepted maximum dose to the spinal cord is 45 Gy in France, compared with more than 50 Gy in some countries. This leaves a margin for delivering an additional dose during a reirradiation.

JM. COSSET - There is no consensus of opinion today on a possible "Time-Dose Factor" applied to a portion of the irradiation delivered previously. In some cases, a compensatory hypertrophy of the non-irradiated part of an organ can improve the functional situation, but in other cases the development of fibrosis is likely to aggravate the situation over time. The problem is particularly relevant with the spinal cord, given the clearly unacceptable risk of radiation-induced myelitis (paraplegia or quadriplegia). Some experts have considered that the conventional threshold of 45 Gy could be exceeded, but this attitude remains the subject of much debate. The individual Radiosensitivity tests currently developed will perhaps enable us in a more or less distant future to exceed, by a small amount and with great caution, the current thresholds.

■ WHAT ARE THE MAIN DIFFICULTIES ENCOUNTERED IN THE TREATMENT OF PATIENTS WITH A RADIOTHERAPY TREATMENT HISTORY?

P. BLANCHARD - The most unfavourable situations are those where it is difficult or even impossible, to retrieve the irradiation history data because the treatment dates back too far or because the data format is incompatible with current equipment. This can lead to delays in treatment or even the decision not to perform radiotherapy due to the lack of sufficient data.

The possibility of future reirradiation is increasingly taken into account as a matter of course, but the definition of the treated volumes nevertheless remains relatively varied.

JM. COSSET - As a general rule, special cases apart (technique only available in a few hyper-specialised centres), patients having to undergo reirradiation are referred in priority to the centre that delivered the first treatment. This guarantees maximum safety in the way the treatment history is taken into account.

Further reading

REIRRADIATION

- **Reirradiation: what are the decision-making criteria?** J.-M. Cosset, C. Chargari, G. Créhange, p526-530, Cancer/Radiothérapie, vol. 23, Issue 6-7 (October 2019) http://dx.doi.org/10.1016/j.canrad.2019.06.007

- **Repair and time factor: example of medullar irradiation.** C. Chargari, P. Maroun, G. Louvel, M. Drouet, D. Riccobono, S. François, F. Dhermain, J.-M. Cosset, É. Deutsch, p547-553, Cancer/Radiothérapie, vol. 21, Issue 6-7, (October 2017) www.sciencedirect.com/science/article/abs/pii/S1278321817303359

- **Recorad: Recommendations for the practice of external-beam radiotherapy and brachytherapy** pS1-S270, e11-e16, vol. 20, supplement (September 2016) www.sciencedirect.com/journal/cancer-radiotherapie/vol/20/suppl/S

- ***Full-dose reirradiation for unresectable head and neck carcinoma: experience at the Gustave-Roussy Institute in a series of 169 patients.*** De Crevoisier R, Bourhis J, Domenge C, et al., p3556-3562, Journal of Clinical Oncology, vol. 16, n° 11 (November 1998) ascopubs.org/doi/10.1200/JCO.1998.16.11.3556

REGULATIONS

- **Decree 2006-6 of 4 January 2006** relative to the hosting of personal health data and amending the Public Health Code www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000264665&categorieLien=id

- ASN Guide No. 5 **Management guidelines for safety and quality in radiotherapy** (April 2009) https://www.french-nuclear-safety.fr/Media/Files/00-Guides/ASN-Guide-No.-5-Management-guidelines-for-safety-and-quality-in-radiotherapy

PATIENT SAFETY

MARCH 2011 - PATIENT IDENTIFICATION

NOVEMBER 2011 - THE FIRST VERIFICATION SESSION

JULY 2012 - HOW DO YOU ANALYSE YOUR SIGNIFICANT RADIATION PROTECTION EVENTS?

APRIL 2013 - WHAT EVENTS MUST BE NOTIFIED TO ASN?

DECEMBER 2013 - IN-VIVO DOSIMETRY

MAY 2014 - LATERALITY ERRORS

MARCH 2015 - RECORD AND VERIFY: RECORDING ERRORS!

JUNE 2015 - PULSED DOSE-RATE AND HIGH DOSE-RATE BRACHYTHERAPY

MAY 2016 - HIGH-PRECISION HYPOFRACTIONATED IRRADIATION

JANUARY 2017 - PROTRACTION / FRACTIONATION

SEPTEMBER 2017 - MAKING THE PATIENT A PARTNER IN TREATMENT SAFETY

JUNE 2018 - PATIENT REPOSITIONING IMAGING: VERTEBRA IDENTIFICATION ERROR

MARCH 2019 - EXPERIENCE FEEDBACK IN OTHER COUNTRIES

JULY 2019 - IMPROVING THE USE OF CT SCANNER FUNCTIONS

MARCH 2020 - SAFETY OF THE RADIOPHARMACEUTICAL CIRCUIT IN NUCLEAR MEDICINE

asn
AUTORITÉ
DE SÛRETÉ
NUCLÉAIRE