PATIENT SAFETY

PAVING THE WAY FOR PROGRESS

#

October 2021

PATIENT FOLLOW-UP FURTHER TO RADIOTHERAPY INCIDENTS

REVIEW OF 10 YEARS OF USE OF THE ASN-SFRO SCALE

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

ÉDITORIAL

Since 2008, the significant radiation protection events (SRPEs) affecting patients undergoing medical radiotherapy procedures are classified on the ASN-SFRO scale, developed by ASN in collaboration with the French Society for Radiation Oncology (SFRO).
This scale, which is dedicated to informing the public, comprises 8 levels: levels 0 to 1 are classified as deviations, levels 2 to 3 as incidents and levels 4 to 7 as accidents. The severity of the effects is assessed by referring to the international clinical classification (CTCAE[1] grades) used by practitioners.

This newsletter is devoted to the retrospective study of patients having suffered an SRPE rated level 2 over the last ten years. The data concerning 57 SRPEs and 112 patients were collected and analysed by a doctoral student in a study marking the 10th anniversary of the ASN-SFRO scale. What conclusions can be drawn from this study?

30% of patients were lost to follow-up; the median follow-up duration is less than two years: the results of this study show that there is still room for progress!

It provides the opportunity for the working group to reiterate the moral obligation, following an SRPE, to follow-up the patient over the long term, beyond the requirements of INCa (French National Cancer Institute) - (approval criterion No. 18).
Professors Gilles Crehange (Curie Institute) and Norbert Ifrah (INCa) share their thoughts on the subject and state their position regarding a national radiotherapy register, allowing monitoring over the long term which is extended to cover innovative devices and new therapeutic practices.

Wishing you enjoyable reading!

The Editorial Team

1 - *Common Terminology Criteria for Adverse Event, Cancer Therapy Evaluation Program, August*

CONTENTS

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- **Publications Director:** Olivier Gupta, Director-General of ASN
- **Chief Editor:** Nathalie Clipet
- **Author:** Minh Nhat Nguyen (medical intern at the Strasbourg Europe Cancerology Institute) and Nicolas Pirault
- **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).
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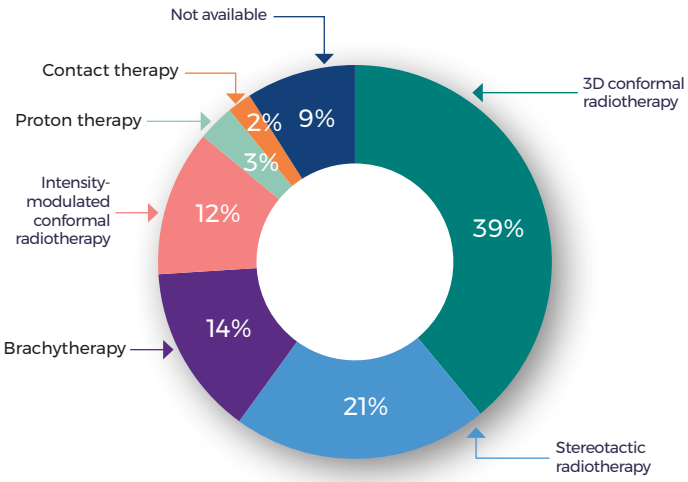
Key figures

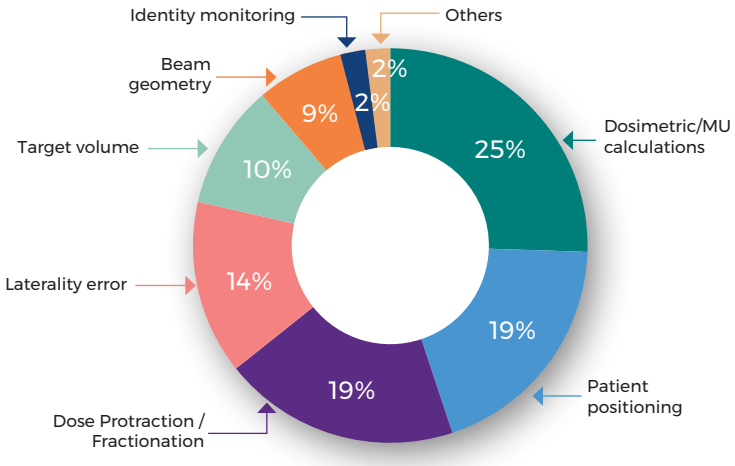
Between January 2008 and December 2018, 57 significant radiation protection events (SRPEs) were rated level 2/2+ on the ASN-SFRO scale, representing 2.5% of all the events reported over the period. 52 SRPEs involved only one patient (level 2), 5 SRPEs concerned a cohort (level 2+), representing a total of 139 patients; no SRPEs were rated level 3 or higher. Over the same period, about 1,700,000 patients received a radiotherapy treatment in a total of about 35,000,000 treatment sessions.

If we establish the profile of the SRPEs of level 2/2+, high-tech external beam radiotherapy comes first among the techniques used, more specifically with 3D conformal radiotherapy (39%) and stereotactic radiotherapy (21%), followed by brachytherapy (14%).

BREAKDOWN OF THE 57 SRPEs



According to the treatment technique



According to types of error

The dosimetric and monitor unit calculations represent one quarter of the causes of SRPEs rated level 2/2+, followed to equal extents by dose protraction/fractionation and positioning errors (19%), laterality errors (14%) and lastly target volume (10%) and beam geometry (9 %) errors.

Background

WHAT ARE THE OBLIGATIONS IN THE EVENT OF AN SRPE?

1. Health professionals involved in the therapeutic treatment or follow-up of patients exposed to ionising radiation for medical purposes are obliged to **notify** events relating to this exposure that could affect the health of the persons "to ASN and to the Director-General of the Regional Health Agency without delay" (article L. 1333-13 of the Public Health Code amended by Ordinance 2016-128 of 10 February 2016 – art. 38).
2. After **analysing** the root causes of the SRPE, a significant event report (SER) is to be sent to ASN within two months.
3. The medical team must **inform** the patient of the harm caused (Article L. 1142-4 of the Public Health Code) and implement **ndividual follow-up of the patient** to detect and treat any complications resulting from the error.

HOW ARE THE SRPEs CLASSIFIED?

The person responsible for the activity proposes an event classification rating on the ASN-SFRO scale based on the notification criteria concerning the confirmed consequences, the dosimetry, the potential effects and the number of patients exposed *(see "To find out more").* This rating is then validated by ASN after consulting the SFRO if necessary.

The rating may be reassessed if the consequences or the number of patients concerned turn out to be greater than initially expected.

WHAT EVENTS ARE RATED LEVEL 2/2+?

Level-2 events are considered to be "**incidents**". The dose received by the patient or the irradiation of a volume is higher than the recommended doses. Unlike level-0 and level-1 events (deviations), which have no expected clinical consequences, they can present **unexpected or unforeseeable acute or delayed effects, but moderate.**

If the number of patients exposed is greater than 1, the incident is rated 2+.

Decoding

A medical error is a particular sensitive subject, as much for the medical staff as for the patient, who are reluctant to relive a difficult period. Twenty-seven cases met with a refusal to take part in the study on the part of the medical centre or the patient. The data collected concerned 122 patients affected by an event of level 2/2+. The following decoding results from the analysis of these data.

LOSS OF MEMORY OF THE INCIDENTS

More than a quarter of the patients have been lost to follow-up (33):

- The retrospective study came up against the first difficulty of identifying patients whose data were anonymised, or for whom the centre has lost the memory or has closed.
- A third of the patients were not subject to specific monitoring, either because their treatment was for palliative purposes, their tumours were benign (osteoma, haemangioma), or again due to events of life (patient relocated, change of referring physician, etc.).

INSUFFICIENT MEDICAL FOLLOW-UP DATA

- The median duration of medical follow-up was 23.5 months, that is to say less than two years.
- Difficulties in obtaining good quality and standardised data (no systematic grading of side effects, truncated follow-up, incomplete medical physics data).

MODERATE DELAYED TOXICITY

After excluding 20 patients in palliative care who died within 6 months following radiotherapy and 12 whose data were unavailable, more than three-quarters of the patients having suffered a radiation protection event showed no signs of delayed toxicity on the date news of them was last received. For more than 11% of them, the grade-1 delayed toxicity corresponds to expected complications resulting from the treatment.

The most severe toxicities, from grade 2 to 4, concern 11.25% of the patients:

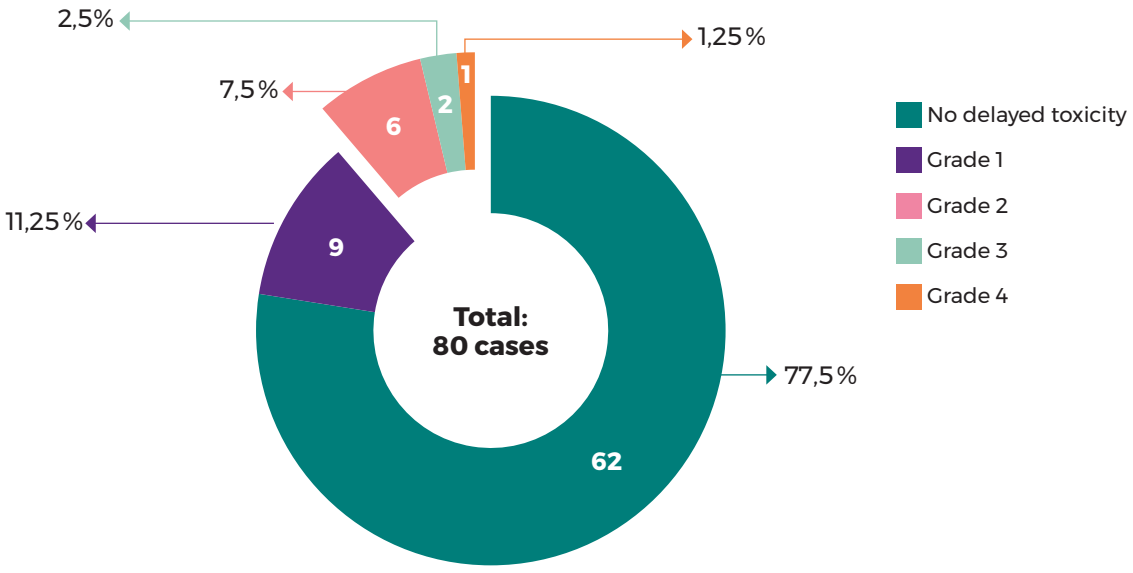
- **6 grade-2 toxicities:** xerostomias (cancer of the hypopharynx, skin cancer), cystitis (cancer of the cervix uteri), anal stenosis (cancer of the anal canal), vaginal stenosis (cancer of the vaginal canal), urinary incontinence and anal incontinence (endometrial cancer);
- **2 grade-3 toxicities:** cystitis and erectile dysfunction (prostate cancer);
- **1 grade-4 toxicity:** radionecrosis of the external acoustic meatus (skin cancer);
- **no grade-5 toxicity** was reported.

Only three toxicities reportedly resulted directly from the radiation protection event: the grade-4 radionecrosis of the external acoustic meatus (linked to a treatment duration calculation error) and the grade-2 vaginal and anal stenosis (linked to fractionation errors).

Several factors might nevertheless have inhibited the appearance or the true impact of the complications:

- **27% of the patients** were in palliative care and therefore their life expectancy was short;
- among the 58 deceased patients, **20 deaths occurred within 6 months** following the radiotherapy treatment, a time frame that is shorter than that defined for complications;
- **more than a quarter of the patients** were lost to follow-up after two years.

BREAKDOWN OF THE DELAYED TOXICITIES



Steps for progress

1 - NOTIFYING THE EVENT AND INFORMING THE PATIENT

Notification of the SRPE remains essential in order to learn lessons from the errors and to identify and correct the identified causes in order to improve radiotherapy practices and patient safety.

For the physician, informing the patient of the confirmed and potential damage can be a source of anxiety and guilt; for the patient this can lead to a breakdown in the relation of trust with their physician; in both cases, medical follow-up of the patient must remain a priority.

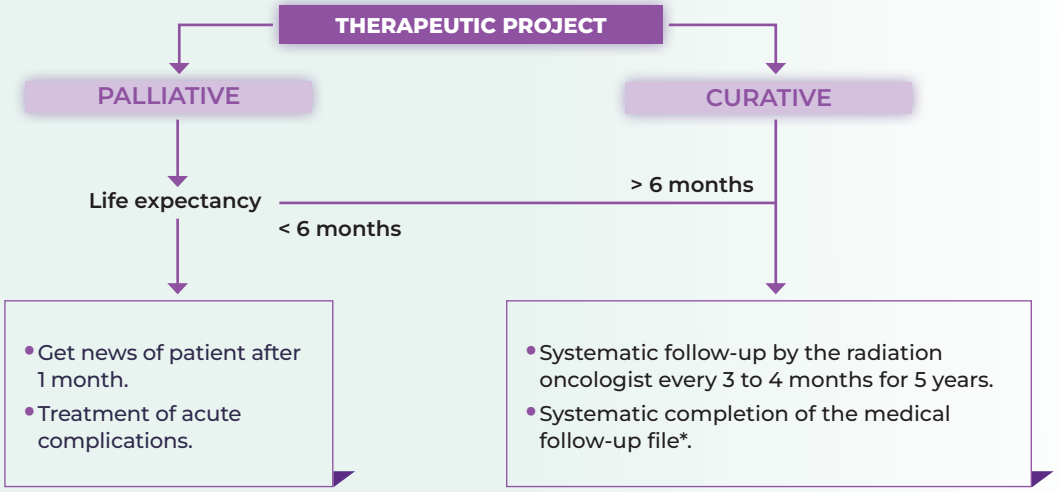
Even if the percentage of reported delayed complications appears reassuring, the insufficient duration of follow-up and the significant share of patients lost to follow-up make a strong case for remaining attentive to the detection and prevention of delayed adverse effects and to improve patient follow-up.

2 - ORGANISING PATIENT FOLLOW-UP FURTHER TO AN INCIDENT

The organisation and frequency of patient follow-up have to be adapted to the clinical context to optimise the assessment of acute or delayed toxicities:

- will the life–expectancy of the patient allow the toxicity to be assessed beyond 6 months?
- by how much are the recommended dose thresholds to the organs at risk exceeded?
- what type of error? What are the delayed effects and risk of over-dosing / under-dosing / induced cancers?

For patients in palliative care, follow-up brought forward to one month will enable acute complications to be treated. For patients undergoing curative treatment, systematic medical follow-up by the radiation oncologist is to be planned over a time frame of at least 10 years, with the patient's medical file being passed on the event of a change of medical centre:



**If there is a change of medical centre, transfer the medical follow-up file to the new referring physician*

In order to optimise the follow-up of these incidents, the working group recommends considering these patients like a prospective cohort and setting up a clinical database centralised in a national register. The criteria to enter into the database should include at least:
- the deviations in dose to the target volume(s) and the organs at risk;
- the acute and delayed toxicities by grade in accordance with CTCAE v5, along with their occurrence time frame.

3 - SYSTEMATISE THE PATIENT'S FOLLOW-UP FILE

Radiotherapy is evolving rapidly, in both the techniques used and professional practices. The medical devices in principle allow for greater precision and better protection of the organs at risk. Nevertheless, their technological promises remain to be demonstrated over the long term, especially when they involve administering high doses per session, as is the case with stereotactic radiotherapy. With this in view, the professionals must define the essential information to include in the patients' standardised files so that a database can be developed and used with rigour.

The experience of the centres

"Monitoring should be realigned on the patients at risk"

Pr. Gilles CREHANGE,
Head of the Radiotherapy Department,
Curie Institute (Paris)

■ In 2013, the Curie Institute was confronted with an SRPE rated level 2+. What have you organised for the follow-up of these patients?

66 patients received an excess does of 3 monitor units during repositioning imaging. The event was rated level 2+ because it affected a cohort. Nevertheless, the individual follow-up of these patients did not raise any particular concerns.

When the event was detected, we recalculated all the doses, informed all the patients concerned in consultation and created a database specifically for their follow-up. The usual follow-up frequency, however, was not changed. After 8 years of follow-up, we have just one case of grade 1 epidermitis.

■ What routine patient monitoring practices do you apply at the Curie Institute?

Cancer monitoring at the Curie Institute is ensured by the radiotherapist in alternation with the surgeon or another specialist of the pathology. With breast cancer, which represents 2/3 of our treatments, the institutionalised care pathway mobilises the radiotherapist at least once a year for 5 years. The follow-up is then continued by the general practitioner. The frequency for other pathologies is often similar.

■ What are the priorities with regard to patient monitoring?

In a context where treatment side effects have fallen drastically thanks to intensity modulation and daily image-guided repositioning, the patients we see in the follow-up consultations are essentially doing well. *Conversely*, a patient who presents risks of relapsing or being less assiduous in their medical follow-up must be able to be monitored for 10 years if there is any doubt about the biological, radiological or clinical markers. Monitoring must be refocused on the patients at risk in order to free time for the preparation of the high-tech treatments. Advanced practice radiographers could be trained for the follow-up of patients who are doing well and identification of those needing a medical examination.

■ Are you in favour of putting in place a national follow-up register for victims of SRPEs of level 2 and higher? And who should be responsible for it?

Yes, as long as the bias of the cohort, where clinical effects are not expected on an individual basis, is avoided. A national register would be a real advantage for the rigorous and uniform long-term follow-up of patients. The patients could be addressed to a group of national experts, with the major drawback of necessitating travel to see the experts. Adopting a more agile approach, the patient could be given one of the e-health applications currently used for the clinical research protocols. Patients can access their follow-up schedule from their smartphone and upload their analysis results. Any anomalies create an alert and the radiation oncologist can receive the patients in follow-up consultation at the appropriate time.

Further reading

NOTIFYING AN SRPE

- **ASN-SRFO scale**
  asn.fr/l-asn-controle/ines-et-asn-sfro
- **Significant patient radiation protection event in radiotherapy: notification and classification on the ASN-SFRO scale.** ASN Guide No. 16
  asn.fr/espace-professionnels/activites-medicales/curietherapie/guides-de-l-asn/guide-de-l-asn-n-16
- **What events must be notified to ASN?** "Patient safety - Paving the way for progress" newsletter of April 2013
  asn.fr/espace-professionnels/retour-d-experience/bulletin-la-securite-du-patient/4-quels-evenements-declarer-a-l-asn
- ***Common Terminology Criteria for Adverse Event, Cancer Therapy Evaluation Program,*** August 2006
  ctep.cancer.gov

The viewpoint of the French National Cancer Institute (INCa)

"Identifying the toxicities of new treatments implies following up the patients over the long term"

Pr. Norbert IFRAH
Chairman of INCa

WHAT POSITION DOES PATIENT FOLLOW-UP OCCUPY IN INCA'S TEN-YEAR STRATEGY FOR FIGHTING CANCER PRESENTED IN FEBRUARY?

It is closely linked to our priority theme N°. 2: limit the sequelae and improve quality of life. With a better survival rate and chronification of the cancer-related complications, the sequelae concern nearly two-thirds of patients 5 years after diagnosis. The stated goal is to reduce this proportion by half.

Cancerology today offers numerous treatment alternatives. If one wants to improve the quality of life of patients while giving them equal chances, it is important to put these therapies - including emerging ones - in competition with one another, as much with regard to their immediate effectiveness as the potential complications. Pain, fatigue, motor or visual impairments, changes in the body image: in three-quarters of the cases, there is no specific medical follow-up concerning the physical or psycho-social sequelae.

WHAT ARE THE CHALLENGES AND THE DESIRABLE DURATION OF PATIENT FOLLOW-UP?

Cancer relapse rates are established after 5 years at international level. This current duration of patient follow-up is far too short to evaluate the toxic cost of new practices or of overtreatment, when there is no longer any detectable residual disease. To give an example, cardiac complications do not appear until 25 to 30 years after the treatment.

We must find ways of ensuring long-term follow-up over time frames exceeding 15 years. There is a dual goal: identify the least obvious late toxicities and the cross-toxicities of mixed therapies combining chemotherapy, surgery and radiotherapy.

WOULD A NATIONAL RADIOTHERAPY REGISTER FULFIL THIS AMBITION TO ENSURE LONG-TERM PATIENT FOLLOW-UP?

INCa is going to put out a call for proposals for the detection and quantification of the sequelae. It will be based on a national register including radiotherapy over an ambitious time frame of 15-20 years. The priority is to collect medical information concerning children and, more broadly, patients with a long life expectancy, especially if this has been obtained through aggressive treatments. A register already exists in paediatrics, but it should be continued after the patients reach adulthood.

WHAT METHODS WOULD BE USED?

INCa favours a register targeting certain specific pathologies and innovative techniques, such as proton therapy or intracranial stereotactic. We are convinced that silo-type (isolated) registers, which are unmanageable for the professionals, must be avoided at all costs. The register must be a "one-stop shop" register covering the entire medical follow-up of the patients and be in an interoperable format. This implies convincing the radiotherapy centres of the scientific and medical interest of the initiative and establishing jointly with them a reasonable number of criteria to be filled out.

With fewer than one thousand medical oncologists in France, long-term patient follow-up will have to be shared between the health professionals of public and private hospitals, the general practitioner, and the social and medical-social professionals, not to mention the patients themselves, who play an active role in their own health care.

PROFESSIONAL RECOMMENDATIONS

- **Announcing treatment-related adverse effects.** HAS Guide of March 2011
  https://www.has-sante.fr/jcms/c_953138/fr/annonce-d-un-dommage-associe-aux-soins
- **Conditions of implementation of new techniques in radiotherapy and the associated practices.** Recommendations of the GPMED and ASN's position
  asn.fr/l-asn-informe/actualites/nouvelles-techniques-en-radiotherapie-et-pratiques-associees

INTERNATIONAL EXPERIENCE FEEDBACK

- **The IAEA database SAFRON** on incidents and near-incidents in radiotherapy
  iaea.org/resources/rpop/resources/databases-and-learning-systems/safron
- **Experience feedback in other countries.** "Patient safety - Paving the way for progress" of March 2019
  asn.fr/espace-professionnels/retour-d-experience/bulletin-la-securite-du-patient/n-13-le-rex-a-l-etranger

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?

DÉCEMBER 2013 - IN-VIVO DOSIMETRY

MAY 2014 - LATERALITY ERRORS

MARCH 2015 - RECORD AND VERIFY: RECORDING ERROR!

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

MAY 2016 - HIGH-PRECISION HYPOFRACTIONATED IRRADIATION

JANUARY 2017 - DOSE 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

SEPTEMBRE 2021 - IONISING RADIATION: LIMITING THE EXPOSURE OF WOMEN UNAWARE OF THEIR PREGNANCY

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