



## Extrahepatic complications following the use of $^{90}\text{Y}$ microspheres to treat liver cancer

**Radioembolisation<sup>1</sup> uses medical devices (DMIA)<sup>2</sup> in the form of microspheres charged with Yttrium-90. Injected as close as possible to liver tumours via the arterial system, they accumulate in the intra-tumour vessels and selectively irradiate the tumours, limiting exposure of healthy tissue. Although this technique is performed under the supervision of experienced physicians, it remains complex. The risks of complications are high, particularly because a hepatopulmonary shunt may occur despite prior simulation. These extrahepatic complications may call into question the organisation of even experienced medical teams.**

**A look back at the lessons to be learned from such an event, to move the culture of radiation protection forward.**

### THE EVENT IN BRIEF

During the follow-up of a patient treated for hepatocellular carcinoma, the day after a SIRT,<sup>1</sup> the nuclear medicine physician observed a heterogeneous tumour distribution and significant pulmonary and digestive fixation on the PET/CT image. Post-therapeutic 3D dosimetry was performed the same day and evaluated average doses at the level of the duodenum at 30 Gy, which was not expected, and at the level of lungs at 27 Gy, instead of the planned 6 Gy. The patient presented no clinical symptoms.

The investigation revealed a 5 mm positional shift of the microcatheter in the hepatic artery between its position during the preparatory phase (phase 1) and that during the treatment phase (phase 2). As the patient has complex arterial vascularisation - with the presence of collateral branches in the vicinity - the identified shift may have had an impact. The patient's referring physician was notified and the patient was monitored regularly. About one month after the SIRT, and then four months later, CT<sup>3</sup> imaging showed lung images compatible with post-radiation lesions, although it was not possible to confirm or refute this hypothesis. The patient was still asymptomatic in both digestive and respiratory terms: he had no post-radiation digestive ulcers and no adverse pulmonary consequences.

<sup>1</sup> Selective Internal Radiation Therapy (SIRT).

<sup>2</sup> Implantable and active medical devices as defined in Art. 2 of Regulation (EU) 2017/745 of 5 April 2017.

<sup>3</sup> Computed tomography (CT scan)

<sup>4</sup> PACS (Picture Archiving and Communications System).

### ANALYSIS OF CAUSES AND INFLUENCING FACTORS

#### Technical factors

- The design of the interventional radiology room is not suitable for SIRT: angiography images of the preparation are not available directly in the room during the treatment phase;
- Preparation and treatment carried out in rooms that do not have the same imaging modalities;
- PACS<sup>4</sup> configuration does not allow microcatheter positioning control scopy series to be automatically sent in order to compare phase 1 images with phase 2 images.

#### Human factors

- Mental workload of interventional radiologists;
- Event leading to displacement of the microcatheter.

#### Organisational factors

- Understaffing of medical and paramedical staff =>
  - Phase 1 and phase 2 carried out by two different interventional radiologists;
  - Interruption of interventional radiologists during their interventions, causing distraction;
  - Offloading of tasks to interventional radiologists that could be performed by the radiographer (due to understaffing);
- Process for checking the positioning of the micro-catheter not formalised;
- Lack of inter/intra-departmental communication following the preparation of each patient prior to treatment.

## BARRIERS PUT IN PLACE BY THE ESTABLISHMENT

- Commissioning an interventional radiology room dedicated to radioembolisation treatments, with equipment enabling images acquired during the treatment phase to be compared with those taken during the preparation phase.
- During the preparation phase, the following steps are performed:
  - an X-ray to check the positioning of the microcatheter at the point of injection of the <sup>99</sup>Tc-labelled albumin micro-aggregates (<sup>99</sup>Tc-MAA);
  - a CBCT/Angio CT to monitor the volume of <sup>99</sup>Tc-MAA perfused.
- During the treatment phase, the following steps are performed:
  - an X-ray to check the positioning of the microcatheter at the point of injection of the <sup>90</sup>Y microspheres;
  - a comparison of radiographs of the position of the microcatheter during the preparation phase and during the treatment phase before injection of the <sup>90</sup>Y microspheres;
  - a CBCT/Angio CT to monitor the volume perfused with <sup>90</sup>Y microspheres.
- Configuring of the PACS to store scopy images.
- Establishing an inter-departmental staff team between interventional radiology and nuclear medicine to systematically discuss the management of each patient, particularly between the preparatory phase and the treatment phase.
- Formalisation of radioembolisation practices, including those previously mentioned.

## ▶ POINTS/PROCESSES THAT WORKED WELL

### 1. ORGANISATIONAL SOLUTIONS

- Accreditation of operators and systematic presence a senior Int. Rd. at SIRT procedures;
- Measurement of the pulmonary shunt and 3D predictive dosimetry to determine the activity to be injected;
- Coordination of teams from the nuclear medicine, medical physics, radiology, gastro-hepatology and pneumology departments, if necessary, to set up immediate treatment and monitor the patient post SIRT.

### 2. TECHNICAL SOLUTIONS

- Availability of PET/CT the day after treatment to perform control imaging for assessing tumour treatment and checking the absence of extrahepatic uptake with systematic 3D dosimetric analysis.

## ▶ ADDITIONAL ACTIONS PROPOSED BY THE REX Working Group

**Considering the potential severity of a high hepato-pulmonary shunt and/or reflux of <sup>90</sup>Y microspheres into the visceral circulation during selective internal radiotherapy, the ASN encourages the nuclear medicine departments that perform them to consider the technical, human and organisational resources required to prevent complications and immediately manage their consequences. The working group on feedback of significant radiation protection events in medical imaging also recommends:**

- Wherever possible, phase 1 and phase 2 should be carried out by the same team;
- Keep scopy images;
- Perform a post-treatment PET imaging check-up including the base of the lungs in the field of view.

<sup>5</sup> The ASN encourages the sharing of experience and strengthening of interactions between establishments using these microspheres to improve therapeutic practices, in particular the implementation of intercomparison studies of the different software for calculating the activities to be administered and the doses delivered in order to move towards harmonised approaches between nuclear medicine departments for personalised dosimetric assessments (Cf. ASN notice no. 2024- AV-0440 of 2 July 2024).



With the participation of IRSN and ANSM