

Regulations and Requirements of Hospitals Performing Radioembolization

C. Trumm, R. T. Hoffmann, T. F. Jakobs, and M. F. Reiser

Contents

1	Introduction	11
1.1	Multidisciplinary Approach.....	11
1.2	Radioembolization Team	11
2	Legal Regulations of Hospitals Performing Radioembolization	12
2.1	Legal Regulations	12
3	Infrastructural Requirements of Hospitals Performing Radioembolization	13
3.1	Appropriate Facilities	13
3.2	Training of Interventional Radiologist	13
3.3	Diagnostic Imaging Equipment.....	13
3.4	Radiation Safety Issues	13
	References	14

Abstract

Centers performing SIRT should ideally be characterized by a multidisciplinary approach to the design, delivery, and reappraisal of primary or metastatic liver cancer treatment, or by referral from a multidisciplinary team familiar with the procedure (Table 1) (Kennedy et al. 2007; Wang et al. 2010). Moreover, the likely interactions between SIRT and any prior, concurrent or planned biological, chemotherapeutic, local or loco-regional ablative, surgical, external beam radiation treatment, or radiosurgery should be extensively discussed within a multidisciplinary tumor board

1 Introduction

1.1 Multidisciplinary Approach

Centers performing SIRT should ideally be characterized by a multidisciplinary approach to the design, delivery, and reappraisal of primary or metastatic liver cancer treatment, or by referral from a multidisciplinary team familiar with the procedure (Table 1) (Kennedy et al. 2007; Wang et al. 2010). Moreover, the likely interactions between SIRT and any prior, concurrent or planned biological, chemotherapeutic, local or loco-regional ablative, surgical, external beam radiation treatment, or radiosurgery should be extensively discussed within a multidisciplinary tumor board.

1.2 Radioembolization Team

According to the recommendations by the radioembolization brachytherapy oncology consortium (REBOC) (Kennedy et al. 2007), the team performing radioembolization should include individuals with sufficient expertise to:

C. Trumm (✉) · M. F. Reiser
Institute of Clinical Radiology, Ludwig Maximilians-University,
Munich, Germany
e-mail: christoph.trumm@med.lmu.de

R. T. Hoffmann
Department and Policlinics of Diagnostic Radiology,
Universitätsklinikum Carl Gustav Carus, Dresden, Germany

T. F. Jakobs
Department of Radiology, Krankenhaus Barmherzige Brüder,
Munich, Germany

Table 1 Mandatory and desirable facilities and personnel for centers performing ^{90}Y radioembolization (according to Dezarn 2008; Kennedy et al. 2007; Wang et al. 2010)

<i>Mandatory</i>
Multidisciplinary team approach to reviewing liver cancer patients, including an interventional radiologist and at least three of
Hepatic surgeon
Medical oncologist
Radiation oncologist
Nuclear medicine physician
Pain physician or anesthetist
Gastroenterologist/hepatologist
Medical physicist/radiation safety officer
Dedicated oncology nursing staff
Established radiation safety, spill, contamination and disposal protocols
Triple phase CT, DSA, and gamma camera $^{99\text{m}}\text{Tc}$ MAA equipment
<i>Desirable</i>
Admitting and clinic rights for radiologists
On-site consultant medical physicist
Magnetic resonance imaging (MRI)
Single photon emission computed tomography (SPECT)
Positron emission tomography (PET)
Hybrid Imaging including PET-CT and PET-MRI

1. Care for the overall medical treatment of the cancer patient
2. Perform vascular catheterization
3. Perform and interpret radiologic scans
4. Assume the responsibility for the delivery of the ^{90}Y microspheres and be the authorized user
5. Monitor radiation safety.

While the interventional radiologist is particularly responsible for the assessment and delivery of the $^{99\text{m}}\text{Tc}$ MAA angiography and radioembolization procedure, further care for the treated patients is usually assumed by the referring clinician or another designated member of the multidisciplinary team (Dezarn 2008).

Before SIRT, the technical complexity, the potential outcomes and complications of the diagnostic workup ($^{99\text{m}}\text{Tc}$ MAA angiography) and the radioembolization procedure should be extensively explained to each patient in a dedicated counselling interview.

Furthermore, during this first clinical appointment the suitability and physical fitness of the patient should be evaluated. Referral for SIRT should never imply an obligation to treat the patient. At least 24 h prior to both the diagnostic $^{99\text{m}}\text{Tc}$ MAA angiography and the radioembolization procedure, patients' written consent should be documented. After SIRT, each case should be reviewed again by the multidisciplinary team in order to inform the team

Table 2 Hospital requirements for initiating a SIRT program

Country	^{90}Y Licence	Specific authority to use radioisotopes in the angiography suite
Germany	x	x
France	x	x
UK	x	x
Belgium	x	x
The Netherlands	x	x
Italy	x	x
Spain	x	—
Switzerland	x	x
Austria	x	x
Sweden	x	—
Norway	x	x
Denmark	x	x
Finland	x	—
Portugal	x	—
Poland	x	—
Slovenia	x	—
Ireland	x	x
Scotland	x	x
Greece	x	x
Turkey	x	—

members with respect to subsequent treatment decisions. Moreover, at discharge the patient should receive recommendations and information on further hydration and nutrition, peri-procedural medication, radiation safety instructions, the next necessary follow-up visits, and contact details in case of post-procedural side-effects.

2 Legal Regulations of Hospitals Performing Radioembolization

2.1 Legal Regulations

In most countries hospitals have to apply for a ^{90}Y license with the appropriate authorities or professional bodies before initiating a SIRT program (Table 2). This license refers to the permission to store and dispose of ^{90}Y in the hospital. In case ^{90}Y isotopes are already used for other therapeutic purposes (e.g., ^{90}Y radiosynoviorthesis) in the hospital, the ^{90}Y license—if defined according to quantity—should be increased in addition to the amount of ^{90}Y currently used in the department (e.g., 8–10 GBq daily, 15–20 GBq monthly).

Beside the ^{90}Y license, a permission for particular users to administer radioisotopes within the radiology department

has to be separately requested from a specific authority (Table 2).

In the United States, ^{90}Y therapy is regulated by the Nuclear Regulatory Commission under the code of federal register (CFR) 10, part 35.1000, as a brachytherapy device (i.e., not a drug) used for permanent brachytherapy implantation therapy (Kennedy et al. 2007). The use of ^{90}Y microspheres is only permitted under the supervision of an authorized user, who must fulfill the training and experience requirements for manual brachytherapy, as well as the specific vendor training in handling of the microspheres and the delivery system. For U.S. institutions performing brachytherapy under a broadscope license, the physician must be authorized by the institutional radionuclide committee. According to Kennedy et al. (2007), interventional radiologists, nuclear medicine physicians and radiation oncologists are sufficiently trained, certified and involved within ^{90}Y treatment programs to use ^{90}Y microspheres. In this context, they would either have to fulfill the training and experience requirements set in CFR 10, part 35.390 (for unsealed sources) or 35.490 (for manual brachytherapy), as well as the specific vendor training.

3 Infrastructural Requirements of Hospitals Performing Radioembolization

3.1 Appropriate Facilities

Radioembolization is a complex and technically demanding procedure. However, emerging centers commonly underestimate the expertise required to safely perform treatments with ^{90}Y microspheres (Wang et al. 2010). First and foremost, a multidisciplinary treatment protocol should be well established before the treatment of the first patient. This includes the structured interaction between diagnostic imaging, nuclear medicine, radiation safety, the multidisciplinary care team, oncology nursing staff, discharge and follow-up procedures, and hospital administration—even if not all of these resources are available at the same site.

3.2 Training of Interventional Radiologist

In addition to absolving the mandatory training by the company delivering the ^{90}Y microspheres, radiologists planning to perform SIRT should initially be instructed at a centre of excellence by a clinical mentor experienced in the procedure, and familiar with the guidelines published by the responsible professional institutions and societies (i.e., Society of Interventional Radiology, Cardiovascular and Interventional Society of Europe) (Dezarn 2008; Murthy

et al. 2005). As soon as the interventional radiologist is sufficiently instructed and practically trained to perform radioembolization at his own institution, he or she should conduct a series of treatments in order to absolve a learning curve experience of his/her own, and optimize the interaction with the local infrastructural resources.

3.3 Diagnostic Imaging Equipment

Although the availability of imaging technology and expertise varies between institutions, the minimal diagnostic workup for SIRT candidates involves the following imaging studies:

- a recent multiphase CT of the liver (performed within 4–6 weeks of angiographic workup)
- digital subtraction angiography (DSA)
- gamma camera $^{99\text{m}}\text{Tc}$ macro-aggregated albumin ($^{99\text{m}}\text{Tc}$ MAA) scanning.

Additional diagnostic information may be provided in selected institutions where the following modalities or imaging techniques are available:

- CT hepatic angiography with intra-arterial contrast-delivery (e.g., cone beam CT)
- Magnetic resonance imaging (MRI)
- Single photon emission computed tomography (SPECT)
- Positron emission tomography (PET)
- Hybrid Imaging including PET-CT and PET-MRI.

3.4 Radiation Safety Issues

In centers performing radioembolization, according to Kennedy et al. (2007) the following radiation precaution guidelines should be followed:

3.4.1 Angiography Suite

- In order to avoid microspheres becoming lodged in crevices from which they are difficult to remove, the floor of the angiography suite should be characterized by a closed surface.
- The angiography suite area underneath the delivery system and the staff involved in dose administration should be draped and plastic covers placed over pedals as a precautionary measure in case of contamination.

3.4.2 Delivery Catheter and Other Devices

- The delivery catheter should be considered radioactive and disposed of with respect to radiation precautions. All other potentially contaminated material (e.g., exit tubing from the dose vial, three-way-valve, etc.) should also be considered radioactive and disposed of equivalently after catheter removal.

- Though not being considered ‘hot’, tubing and syringes to deliver and flush the catheter sheath should be checked for radioactivity before routine disposal.

3.4.3 Staff

- Pregnant staff and/or pregnant family members should be excluded from the procedural or post-procedural care of ^{90}Y patients.
- Infusion personnel must remain behind the delivery system containing the dose. Anyone assisting should remain clear of the tubing connected to the catheters.
- The administering staff should wear double gloves, double shoe covering and protective eye-wear.
- All personnel within the angiography suite must have their shoe covers checked for radiation at the end of the procedure and before leaving the suite. The suite must be checked at the end of the procedure after all contaminated waste and the patient have been removed from the room to rule out any radiation contamination.

3.4.4 Patient

- Because ^{90}Y resin microspheres may have trace amounts of free ^{90}Y on their surface, which can be excreted in the urine in the first 24 h, patients are advised to wash their hands after voiding. In contrast, ^{90}Y glass microspheres are not known to have free ^{90}Y in trace amounts in the treatment vial, and therefore no specific precautions are

required for handling the urine of patients treated with ^{90}Y glass microspheres.

- At discharge, the patient should be given a letter confirming that they have received radiation internally. In addition, a wristband indicating the isotope given, the date of delivery, and a contact number for questions may be advantageous.

References

- Dezarn WA (2008) Quality assurance issues for therapeutic application of radioactive microspheres. *Int J Radiat Oncol Biol Phys* 71(1 Suppl):S147–S151
- Kennedy A, Nag S, Salem R, Murthy R, McEwan AJ, Nutting C, Benson A 3rd, Espat J, Bilbao JJ, Sharma RA, Thomas JP, Coldwell D (2007) Recommendations for radioembolization of hepatic malignancies using yttrium-90 microsphere brachytherapy: a consensus panel report from the radioembolization brachytherapy oncology consortium. *Int J Radiat Oncol Biol Phys* 68(1):13–23
- Murthy R, Nunez R, Szklaruk J, Erwin W, Madoff DC, Gupta S, Ahrar K, Wallace MJ, Cohen A, Coldwell DM, Kennedy AS, Hicks ME (2005) Yttrium-90 microsphere therapy for hepatic malignancy: devices, indications, technical considerations, and potential complications. *Radiographics* 25(Suppl 1):S41–S55
- Wang SC, Bester L, Burnes JP, Clouston JE, Hugh TJ, Little AF, Padbury RT, Price D (2010) Clinical care and technical recommendations for ^{90}Y microsphere treatment of liver cancer. *J Med Imaging Radiat Oncol* 54(3):178–187

Liver Radioembolization with ^{90}Y Microspheres

Bilbao, J.I.; Reiser, M.F. (Eds.)

2014, XIII, 188 p. 125 illus., 25 illus. in color., Hardcover

ISBN: 978-3-642-36472-3