Clinical and dosimetric considerations for yttrium-90 glass microspheres radioembolization of intrahepatic cholangiocarcinoma, metastatic colorectal carcinoma, and metastatic neuroendocrine carcinoma: Recommendations from an international multidisciplinary working group

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Online Resources

Online Resource 1: Degree of recommendation

Degree	Meaning
A	Strongly recommended (good evidence that the measure is effective, and benefits outweigh the harms)
B	Recommended (at least moderate evidence that the measure is effective, and benefits exceed harms)
C	No recommendation for or against (at least moderate evidence that the measure is effective, but benefits are similar to harms and a general recommendation cannot be justified)
D	Recommended against (at least moderate evidence that the measure is ineffective or that the harms exceed the benefits)
E	Insufficient, low quality or contradictory evidence (the balance between benefit and harms cannot be determined)

Online Resource 2: Strength of consensus

Strength of consensus	% consensus
Strong	≥80
Moderate	50–79
Weak	≤49

Online Resource 3: Methods

Dosimetry planning for yttrium-90 (^{90}Y) glass microspheres is proposed with a mean dose approach, i.e., aiming for an average dose over either single or multicompartment volumes of interests (VOIs). Published data is limited on voxel-based dosimetry (non-uniform distribution), therefore voxel-based dosimetry was not included in the current recommendations [1].

Technetium-99 macroaggregated albumin ([^{99m}Tc]TcMAA) is administered during the mapping angiogram to assess lung shunting, potential extrahepatic non-target deposition through hepatico-enteric collateral vessels and intrahepatic multicompartment distribution of activity. [^{99m}Tc]TcMAA tumour uptake may be variable across tumour types. Typically, neuroendocrine tumours (NET) has a high tumour uptake, metastatic colorectal cancer (mCRC) has a low tumour uptake while intrahepatic cholangiocarcinoma

(iCCA) may have variable tumour uptake [2]. The scout dose [^{99m}Tc]TcMAA may be injected in the proper hepatic artery, selectively in both lobes, or selectively in one lobe (highest burden). However, it is important to recognize that in order to implement [^{99m}Tc]TcMAA for intrahepatic dosimetry (multicompartment dosimetry; MCD), injection of [^{99m}Tc]TcMAA and ^{90}Y glass microspheres should be performed at the same angiographic position, minimizing the influence of vessel bifurcations, i.e., preferential flow, and injected slowly (20–30 seconds), in order to mimic microsphere infusion [3]. It is important to note that [^{99m}Tc]TcMAA overestimates lung shunting. This overestimation is large and systematic especially when planar imaging is used [1]. SPECT/CT provides more accurate lung shunting assessment, but differences in MAA particle size and free [^{99m}Tc]TcPertechnetate will result in overestimation [1]. According to SPECT/CT evaluation, lower dose threshold should be used (<30 Gy planar, <20 Gy SPECT/CT) [4-7]. Contemporary practice also supports the use of post-therapy imaging with ^{90}Y bremsstrahlung SPECT/CT or ^{90}Y PET/CT with the intent to (1) verify dose delivery and distribution, (2) gain information that facilitates calculation of normal tissue absorbed dose (NTAD) and tumour absorbed dose (TAD), thereby assisting with expectation of clinical response or complications, and (3) have information that can be used as an input for retreatment dosimetry [7].

Key definitions used throughout this document are identical to those in the hepatocellular carcinoma (HCC)-related recommendations [8, 9]:

- **Mean absorbed dose:** quantity expressed in Gray (Gy) to describe the average amount of energy (joules) deposited within a specific VOI with a given mass (kg). The mean absorbed dose is often referred to as “Dose” and must not be mistaken for “Activity” or “Dosage” (GBq) [10, 11].

- **MIRD schema:** The Medical Internal Radiation Dose (MIRD) schema is applicable to both the single compartment dosimetry (SCD) and MCD models. The mean absorbed dose (D) in any specific VOI (i.e., perfused volume, lobe, tumour or normal tissue) with mass of any VOI, denoted as M, with the assumption that D is distributed uniformly in each volume with permanent

microsphere implantation and no biological clearance [12, 13]. Using this schema, D in a VOI is computed as:

$$D_{(\mathrm{Gy})} = \frac{A_{(\mathrm{GBq})} \times (50_{(\mathrm{Gy\ x\ kg/GBq})}(1 - F)}{M_{(\mathrm{kg})}}$$

where A is the net activity of ^{90}Y in the VOI, and F is the lung shunt fraction [14, 15].

- **Single compartment model:** In the single compartment model, only the averaged absorbed dose value over the treated liver volume can be calculated, neglecting the difference in microsphere distribution patterns (especially between tumours and normal liver). This represents a simplification of the real distribution. Hypervascular tumours will receive a higher dose, and the normal parenchyma will receive a lower absorbed dose [16-19].
- **Multicompartment model:** A dosimetry model, based on the MIRD schema, where D is determined in more than one VOI, such as the tumour VOI and the normal parenchyma VOI. Partition modelling refers to the MCD approach reporting the tumoural and non-tumoural doses separately with a single averaged tumour to averaged non-tumoural uptake ratio (T:N ratio) [15, 19, 20].

Online Resource 4: Recommendations for mCRC, mNET and iCCA

Treatment Intent	1. Liver function should be preserved, and radioembolization-induced liver disease (REILD) and late onset liver toxicities including liver fibrosis should be prevented, especially in situations where expected survival is long enough that subsequent treatment is possible (e.g., surgery in the setting of radiation lobectomy, repeat radioembolization, local ablative therapies, or systemic therapy). For this purpose, except in case of superselective treatment, it is advocated to use multicompartment dosimetry and plan whole normal liver dose below safety limits, considering risk factors (baseline liver function, lobar therapy in patients with portal hypertension, previous chemotherapy lines, or other hepatotoxic treatments). 2. Exceptions to palliative intent treatment include radiation segmentectomy with the intention of complete tumour ablation (i.e., treatment of up to two Couinaud

	segment(s) or up to 25% whole liver volume) [21], and radiation lobectomy with the aim to control ipsilateral disease and induce contralateral hypertrophy in preparation for potential resection. Ablative or bridge to resection intent have implications for treatment planning and dosimetry (see below). Since major portions of the liver remain untreated in these situations (i.e., safety assurance), treatment is geared towards maximal efficacy of the treated volume. 3. The intent of radiation segmentectomy is complete tumour ablation [22, 23]. At these high ablative absorbed dose levels, treatment effect relies less on tumour type and will be effective in non-HCC tumours [13, 24-27]. 4. Radiation lobectomy applies to patients who are potential resection candidates, but: a) have inadequate future liver remnant (FLR), and/or b) need an embedded test-of-time to better define tumour biology, and/or c) need the treated tumour to be retracted from the hepatic vein and/or inferior vena cava, and/or d) need demonstration of a tumour response prior to surgery [28, 29].
Patient Selection	1. Life expectancy of ≥3 months, ECOG score 0-1 [24, 30, 31]. 2. Patients should have sufficient liver function (i.e., aspartate aminotransferase or alanine aminotransferase <5 times upper limit of normal (ULN), INR ≤1.5, albumin ≥3.0 g/dL and normal bilirubin). Treatment is contraindicated when bilirubin exceeds normal levels and is not caused by biliary obstruction, especially in bilobar metastatic disease, where whole liver treatment is warranted [31, 32]. In case of more severe hepatic dysfunction, consider multidisciplinary discussion on individualized patient characteristics and consider other treatment options. 3. Sufficient renal function to allow for angiography (i.e., creatinine clearance >30 ml/min). No data in patients on dialysis is available. 4. Pretreatment [^{99m}Tc]TcMAA distribution may be part of patient selection. In case of grossly inadequate TAD and/or overtly unacceptable NTAD, patients should not be treated because of futility and/or safety concerns, respectively. It should be noted: 1) [^{99m}Tc]TcMAA may not always be a reliable predictor of post-treatment distribution, 2) specific dose thresholds are preliminary (see below), and 3) pretreatment CT/MRI alone is insufficient to determine vascularity/suitability. 5. Tumours abutting the colon, gallbladder and stomach can usually be safely treated in the absence of prior resection or adjuvant, high-dose radiation, which may cause adherence of these structures and potential collateral damage. Extrahepatic radiation toxicity to adjacent structures has been demonstrated in only a few case reports [33-35]. In the setting of biliary stents post-sphincterotomy, administration of prophylactic antibiotics is recommended due to risk of abscess formation [36].
Treatment Planning	Multiple variations of [^{99m}Tc]TcMAA administration exist. Options include [9]: 1. Inject [^{99m}Tc]TcMAA in the proper hepatic artery to perfuse the entire liver. This approach is sufficient for lung shunt fraction estimation, but may not be accurate for dosimetry purposes in case treatment is delivered in a selective approach (i.e., not in the proper hepatic artery, but in the right and left hepatic artery selectively).

	2. Injection in the lobe with higher tumour burden. This option is used for superselective approaches to limit the number of catheterizations of the small segmental branch, perfusing tumour [37]. This approach is sufficient for lung shunt fraction estimation (most conservative), and the contralateral lobe, but may not be accurate for dosimetry purposes. 3. Injection in both lobes with a split vial of [^{99m}Tc]TcMAA into right and left hepatic arteries (ideal for MCD) [38]. To optimize MCD treatment planning the catheter position for [^{99m}Tc]TcMAA and TheraSphere should be consistent [39]. 4. The nominal [^{99m}Tc]TcMAA activity is 150 MBq (e.g., 100 MBq injected in the right lobe; 50 MBq injected in the left lobe). Note: the interval between preparation and administration does not influence MAA distribution, but the interval between administration and imaging does. Biodegradation, leading to higher extrahepatic activity (e.g., lung shunt fraction, thyroid, kidneys and stomach) starts immediately after administration [39]. 5. Acceptable lung absorbed dose is 30 Gy for a single treatment and 50 Gy cumulative for multiple treatments, based on planar [^{99m}Tc]TcMAA scintigraphy. However, dose-effect relationships have not been established (because of low incidence of radiation-induced pneumonitis, <1 %). Furthermore, It is generally recognized that 1) [^{99m}Tc]TcMAA in SPECT/CT largely overestimates the lung shunt fraction, 2) [^{99m}Tc]TcMAA quantification on planar scintigraphy largely overestimates the lung activity (in part because of lack of attenuation correction), and 3) [^{99m}Tc]TcMAA lung shunt fraction increases at longer intervals between administration and imaging. Intra-procedural CT (cone-beam CT or Angio-CT) It is highly recommended to use a cross-sectional technique during the mapping procedure: 1. General: to identify extrahepatic perfusion from hepatico-enteric vessels and to determine the perfused volume(s). 2. Radiation segmentectomy: to determine angiosome volume by cone-beam CT or angio-CT [22, 23].
Strength of Recommendation	B
Degree of Consensus	Strong

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