



ACMUI's Views on Yttrium-90 Microsphere Brachytherapy

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Y-90 Microsphere Brachytherapy

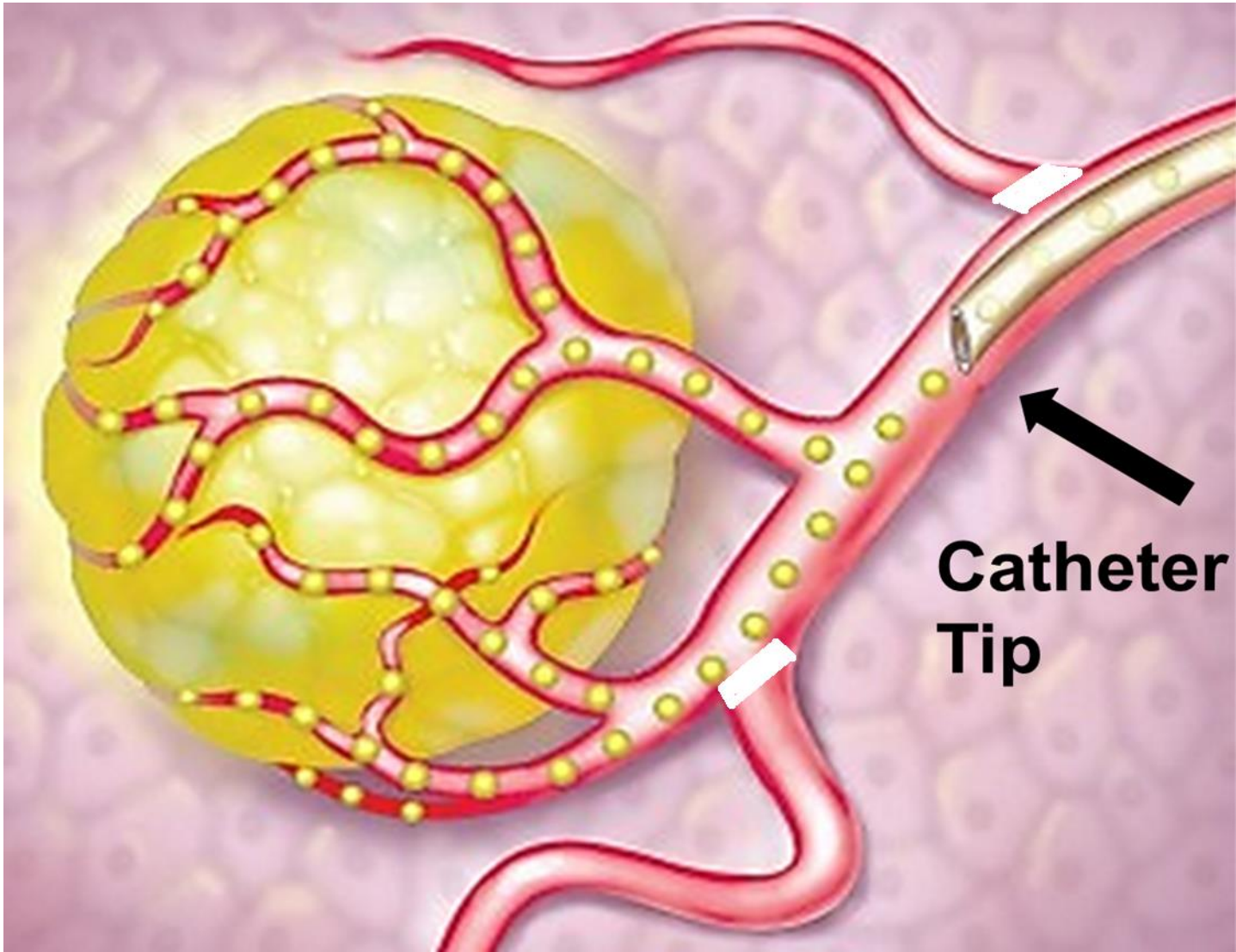
Treatment of Liver Tumors

- **Radiation Therapy for unresectable or chemotherapy-unresponsive liver tumors**
 - **Symptom Palliation**
 - **Improve Survival**
 - **Improve time to progression**
 - **Pre-Transplant Bridge Therapy**
 - **Tumor Regression (therapy adjunct)**
 - **Curative**

Y-90 Microsphere Brachytherapy

Procedure Rationale

- **Y-90 MS are injected through a catheter selectively positioned in the hepatic artery or its branches supplying the liver tumor(s)**
- **The MS are too large to pass through the capillaries and become permanently trapped in the tumor next to malignant cells**
- **The Y-90 MS deliver a therapeutic radiation dose to the tumor**



Y-90 Microsphere Brachytherapy

Safety & Effectiveness

- **Each patient must meet strict selection criteria**
- **Procedure must be meticulously individualized for each patient**
- **Technical success depends on detailed patient preparation and intervention to**
 - **Ensure accurate delivery of the planned dose(s) to the liver tumor(s);**
 - **Minimize/eliminate the known risks of activity deposition in non-target tissues, including *the Lung and GI tract***

ACMUI Y-90 Microsphere Subcommittee *Charge*

- **To determine whether and under what conditions the deposition of intra-arterial Y-90 microspheres (MS) in the Gastrointestinal (GI) tract constitutes a reportable medical event, specifically as regards notation of such expectation in the written directive**

ACMUI Y-90 Microsphere Subcommittee Charge

- **To develop recommendations for any relevant changes to current Y-90 Microsphere Brachytherapy Licensing Guidance (2012)**

ACMUI Y-90 Microsphere Subcommittee Expanded Charge

- **At the discretion of the subcommittee,**
- **To determine whether additional medical event issues unrelated to GI deposition of Y-90 MS require consideration, and**
- **To offer recommendations for related Regulatory Guidance change**

Subcommittee Conclusion

The Subcommittee members unanimously agreed that revising the current Y-90 Microsphere Brachytherapy Guidance (2012) is in order to align with (1) the unique characteristics of Y-90 MS brachytherapy, (2) the advances and improvements made in the procedural interventions to eliminate or manage non-target MS deposition and (3) current medical practice of Authorized Users and treatment teams.

Subcommittee Conclusions

- **Prescribed activity and actual infused treatment activity are the most appropriate metrics for regulatory purposes**
- **Medical event reporting criteria should be based on a readily determined differential between the prescribed activity stated in the written directive and the actual treatment activity infused**

Recommendations

Change to Guidance

- **Specification of an “acceptable” GI tract and lung dose/activity in the written directive prior to performance of the Y-90 microsphere embolization procedure should NOT be required**
- **Instead, a total treatment activity of Y-90 microspheres to be administered should be the required compliance measure for organs and tissues other than the treatment site**

Recommendations

Change to Guidance

Implantation of the MS brachytherapy sources is considered to be in accordance with the WD, if

- The total administered/infused activity does not vary from the activity prescribed in the written directive by 20% or more;**
- Except in situations in which the activity administered is limited by termination of the procedure due to stasis**

Recommendations

Implementation

- **The recommendations should be incorporated into NRC guidance for Y-90 microsphere brachytherapy**
- **The NRC staff, in consultation with ACMUI, compose and disseminate explanation of these recommended revisions in a manner best suited to both the NRC as well as to AUs and other stakeholders tasked with compliance**

Summary

- **This modality is regulated under 10 CFR 35.1000**
- **Guidance can be changed without a rule change**
- **ACMUI's advice to the staff is a frequent and integral part of the process.**
- **This advice that ACMUI has provided to staff on needed changes to the Y-90 guidance is a prime example of the value added by the ACMUI.**

Acronyms

- **10 CFR – Title 10 Code of Federal Regulations**
- **ACMUI – Advisory Committee on the Medical Uses of Isotopes**
- **AU – Authorized User**
- **GI – Gastrointestinal**
- **MS – Microspheres**
- **NRC – US Nuclear Regulatory Commission**
- **WD – Written Directive**
- **Y-90 – Yttrium-90**