

**American College of Radiology
ACR Appropriateness Criteria®**

Clinical Condition: Radiologic Management of Hepatic Malignancy

Variant 1: Hepatocellular carcinoma: Solitary tumor <3 cm.

Treatment/Procedure	Rating	Comments
Systemic chemotherapy	3	
Resection	8	
Transplantation	9	
Chemical ablation	5	
Thermal ablation	8	
Stereotactic body radiotherapy (SBRT)	5	
Transarterial embolization (TAE)	5	
Transarterial chemoembolization (TACE)	5	
Selective internal radiation therapy (SIRT)	5	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Variant 2: Hepatocellular carcinoma: Solitary tumor 5 cm.

Treatment/Procedure	Rating	Comments
Systemic chemotherapy	3	
Resection	8	
Transplantation	9	
Chemical ablation	3	The tumor is too large for chemical ablation. This procedure can be used instead of or in addition to thermal ablation, depending on the tumor location.
Thermal ablation	5	
Stereotactic body radiotherapy (SBRT)	4	
Transarterial embolization (TAE)	6	
Transarterial chemoembolization (TACE)	7	This procedure refers to either conventional TACE or DEB-TACE.
Selective internal radiation therapy (SIRT)	7	This procedure is especially applicable in portal vein thrombosis or extensive bilobar disease.
Transarterial chemoembolization (TACE) combined with thermal ablation	7	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Clinical Condition: Radiologic Management of Hepatic Malignancy**Variant 3: Hepatocellular carcinoma: More than 1 tumor, at least 1 of them >5 cm.**

Treatment/Procedure	Rating	Comments
Systemic chemotherapy	6	Consider this procedure for patients not amenable to other localized therapies.
Resection	5	Consider resection following neoadjuvant TAE or TACE in the noncirrhotic patient.
Transplantation	1	
Chemical ablation	2	
Thermal ablation	3	This procedure depends on local expertise.
Stereotactic body radiotherapy (SBRT)	3	
Transarterial embolization (TAE)	7	
Transarterial chemoembolization (TACE)	8	This procedure refers to either conventional TACE or DEB-TACE.
Selective internal radiation therapy (SIRT)	8	
Transarterial chemoembolization (TACE) combined with thermal ablation	6	Early evidence is promising. More data are needed.
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Variant 4: Intrahepatic cholangiocarcinoma: 4 cm in diameter, no evidence of biliary obstruction.

Treatment/Procedure	Rating	Comments
Systemic chemotherapy	8	
Resection	8	
Transplantation	5	
Chemical ablation	3	
Thermal ablation	5	
Stereotactic body radiotherapy (SBRT)	4	
Transarterial embolization (TAE)	4	
Transarterial chemoembolization (TACE)	5	
Selective internal radiation therapy (SIRT)	5	
Transarterial chemoembolization (TACE) combined with thermal ablation	5	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Clinical Condition: Radiologic Management of Hepatic Malignancy

Variant 5: Metastatic liver disease: Multifocal metastatic neuroendocrine tumor (includes carcinoid tumors as well as islet cell tumors of the pancreas).

Treatment/Procedure	Rating	Comments
Long-acting octreotide	9	
Systemic chemotherapy	3	
Resection	3	
Transplantation	2	
Chemical ablation	1	
Thermal ablation	3	
Stereotactic body radiotherapy (SBRT)	2	
Transarterial embolization (TAE)	7	
Transarterial chemoembolization (TACE)	8	DEB-TACE potentially carries a higher risk of biloma formation.
Selective internal radiation therapy (SIRT)	8	
Transarterial chemoembolization (TACE) combined with thermal ablation	5	Early evidence is promising. More data are needed.

Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate

Variant 6: Metastatic liver disease: Multifocal colorectal carcinoma (liver dominant or isolated).

Treatment/Procedure	Rating	Comments
Systemic chemotherapy	9	
Resection	6	
Transplantation	1	
Chemical ablation	1	
Thermal ablation	2	
Stereotactic body radiotherapy (SBRT)	2	
Hepatic arterial chemotherapy infusion	5	
Transarterial embolization (TAE)	6	
Transarterial chemoembolization (TACE)	6	
Selective internal radiation therapy (SIRT)	7	
Transarterial chemoembolization (TACE) combined with thermal ablation	5	This procedure depends on the tumor burden.

Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate

Clinical Condition: Radiologic Management of Hepatic Malignancy**Variant 7: Solitary colorectal liver metastasis.**

Treatment/Procedure	Rating	Comments
Systemic chemotherapy	9	This procedure is appropriate alone and with resection.
Resection	9	
Transplantation	1	
Chemical ablation	2	
Thermal ablation	8	This procedure is recommended if the tumor is <3–5 cm. Use of this procedure depends on local expertise.
Stereotactic body radiotherapy (SBRT)	5	
Hepatic arterial chemotherapy infusion	4	
Transarterial embolization (TAE)	5	
Transarterial chemoembolization (TACE)	6	This procedure may be especially useful for downstaging patients for more definitive therapies. Conventional TACE is not as well established for this indication, but DEB-TACE with irinotecan shows early promise and is being investigated further.
Selective internal radiation therapy (SIRT)	6	This procedure is often used after failure of 1 or more lines of systemic therapy. However, prospective studies are pending which may show a benefit to moving SIRT earlier in the treatment algorithm.
Transarterial chemoembolization (TACE) combined with thermal ablation	6	Early evidence is promising. More data are needed. This procedure may be especially useful for downstaging patients for more definitive therapies.
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

RADIOLOGIC MANAGEMENT OF HEPATIC MALIGNANCY

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Summary of Literature Review

Introduction/Background

Management of hepatic malignancy remains a challenging problem. Depending on the clinical scenario, traditional therapies such as resection, systemic chemotherapy, and external beam radiation are either unavailable or ineffective. To help fill this void, a number of techniques have been developed by interventional radiologists to treat hepatic malignancy. These treatments include direct tumor ablation via chemical or thermal means and endovascular techniques such as embolization, chemoembolization, and radioembolization with yttrium-90 (Y90). The role of these treatments in the management of primary and secondary hepatic malignancy is reviewed below.

Discussion by Variant

Variants 1–3: Primary hepatic malignancy; hepatocellular carcinoma

Despite marked advances in interventional oncology over the past decade, the preferred first-line treatment for hepatocellular carcinoma (HCC) remains liver transplantation when proper indications are met [1,2]. Unfortunately, the number of patients awaiting transplant far outstrips the number of available organs. Patients younger than age 65 with a limited tumor burden (conventionally defined by the Milan criteria as 1 tumor measuring ≤ 5 cm or up to 3 tumors all measuring < 3 cm) should undergo evaluation for transplantation [3]. Resection also offers acceptable long-term survival in suitable patients, often defined as those with low-volume tumor burden, well-preserved liver function, and no significant portal hypertension [4].

Systemic therapy [5] and radiation therapy [6] have traditionally been ineffective in treating HCC. Marginal therapeutic improvement has been accomplished in recent years with the development of sorafenib, a multikinase inhibitor. A double-blinded randomized study of sorafenib versus placebo in patients with HCC demonstrated a statistically significant difference in median overall survival: 10.7 months for those taking sorafenib compared to 7.9 months for those taking placebo [7]. Nevertheless, since many patients are not candidates for surgery and in light of the relative ineffectiveness of other treatments, percutaneous therapies often play a central role in the management of HCC. These therapies can be categorized as either ablative or transarterial techniques.

Ablative therapies are typically divided into 2 groups: chemical and thermal. Chemical ablation is accomplished by injection of a tumoricidal agent, typically absolute alcohol, directly into the tumor under imaging guidance. Thermal ablation commonly refers to radiofrequency ablation (RFA), but other techniques include cryoablation and microwave ablation. Ablative therapies can be performed either percutaneously or surgically, using open or laparoscopic methods. RFA has been shown to be a more effective ablative therapy than percutaneous ethanol injection (PEI) for treating HCC [8]. However, PEI may still have a legitimate role for treating tumors adjacent to critical structures that would be at higher risk of injury with RFA [9,10]. Microwave ablation has also shown promise for this indication [11]. There is also theoretical justification to suggest microwave ablation may carry certain advantages when compared to RFA. These potential advantages include a decreased susceptibility to heat sink from adjacent large vessels, increased ability to supply thermal energy through desiccated tissue, and the

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potential to create larger ablation zones in a shorter period of time [12]. Justification for the use of cryotherapy in treating HCC is currently not as well supported [13].

Ablative therapies are typically most effective at treating small HCCs (≤ 3 cm in diameter) [14-16]. As tumor diameter increases above 3 cm, treatment results improve when ablation is combined with chemoembolization rather than being used as a stand-alone treatment [17]. Additionally, although ablative therapies have traditionally been viewed as only palliative, recent research has demonstrated their potential to offer equivalent opportunities for overall survival relative to surgical resection in certain clinical scenarios [18-24]. Ablative therapies are also now commonly used as a neoadjuvant therapy intended to “downstage” or bridge patients to transplant or resection. In this role, ablative therapies have been found to effectively decrease the dropout rate for liver transplant, but published evidence is inconclusive as to whether this effectively improves patient survival [25,26]. Recently, stereotactic body radiation therapy (SBRT) has emerged as a potential alternative to percutaneous ablative techniques for all of the above indications [27-29].

As tumor number and/or size increases, transarterial therapy is more commonly indicated [30]. A variety of endovascular techniques have been developed to treat HCC. These include transarterial embolization (TAE) with embolic particles alone, transarterial chemoembolization (TACE), and selective internal radiation therapy (SIRT). Exclusion criteria for these techniques often focus on the extent of underlying liver disease and tumor burden [31,32]. Surprisingly, given the theoretical risk of rendering the liver globally ischemic, hepatic arterial embolization techniques tend to be well tolerated even in the setting of portal vein thrombosis [33,34].

Several trials have demonstrated a significant survival benefit with the use of TACE for HCC compared to best supportive care [35-37]. There is limited evidence that TAE may have similar efficacy as TACE; however, in practice TACE appears to be typically favored by most operators [38-40]. TACE has also been studied as a neoadjuvant therapy to transplantation or resection. As with RFA, recent studies suggest TACE may control tumor progression, thereby decreasing transplant list dropout rates. However, the survival benefit of this technique is still debated despite present data suggesting a positive impact of bridging treatments on both tumor recurrence and patient/graft survival following transplantation [41-47]. Recently, TACE has been further refined through the development of drug-eluting beads as the embolic agent. Several studies have suggested that this agent may be more efficacious with less systemic toxicity than the established conventional TACE technique of direct infusion of chemotherapeutic agents emulsified in ethiodized oil, followed by bland embolization [48-51].

SIRT with beta-emitting Y90 beads is another widely accepted treatment option for patients with HCC [52,53]. Outcomes with this new agent are similar to those described with TACE and TAE, with the possible advantage of less patient discomfort and toxicity [54-58]. SIRT has also shown the ability to effectively downstage patients for potential transplant or resection [59,60]. Potential disadvantages to SIRT compared to TACE and TAE include the need for more extensive arteriography for treatment planning as well as additional logistical hurdles and cost involving dose planning.

Therapeutic regimens using different combinations of ablative techniques, transarterial techniques, systemic therapy, and surgical treatments are also commonly utilized, given the theoretical benefits of a multifaceted treatment regimen compared to monotherapy [61-66].

Variant 4: Intrahepatic cholangiocarcinoma: 4 cm in diameter, no evidence of biliary obstruction

Cholangiocarcinoma is an epithelial cancer of the biliary duct system. Resection is the only commonly accepted potentially curative treatment modality; however, in most cases the tumor is not resectable at the time of diagnosis [67]. Unlike with hepatocellular carcinoma, transplantation is not widely considered a reasonable option due to poor results from prior studies [68]. Nevertheless, the Mayo Clinic has demonstrated a survival advantage in a select subset of patients with small (< 3 cm) hilar cholangiocarcinoma in the setting of underlying primary sclerosing cholangitis when combined with neoadjuvant chemoradiation. These results have not yet been shown to be generalizable to other centers [69].

Systemic therapy with combination gemcitabine and cisplatin has been shown to increase survival. Nevertheless, the impact of chemotherapy on survival remains modest, with median overall survival being approximately 11.7 months [70]. After gemcitabine/cisplatin therapy, there is essentially no known effective chemotherapy. The poor response of cholangiocarcinoma to current systemic therapy highlights the need for the development of more effective liver-directed therapy.

Several small studies have been published in recent years which demonstrate the potential for increased survival both with ablative therapies as well as transarterial therapies. With respect to thermal ablation, there is evidence that both microwave and RFA are potentially effective therapeutic modalities, particularly for tumors with a diameter <5 cm [71,72]. Likewise, survival benefit has also been demonstrated through the use of transarterial therapies such as radioembolization and chemoembolization [73-76]. There is limited evidence that drug-eluting bead chemoembolization may be more effective than conventional chemoembolization for this indication [77]. As with other types of hepatic malignancy, hepatic arterial chemoinfusion (HAI) has also been shown in small series to improve overall survival. However, the applicability of this technique is hindered by cost, potential complications, and other logistical hurdles [78].

Variants 5: Metastatic liver disease: Multifocal metastatic neuroendocrine tumor (includes carcinoid tumors as well as islet cell tumors of the pancreas)

Neuroendocrine tumors include carcinoid tumors that arise from the small bowel, appendix, lung, bronchi, and pancreas as well as pancreatic islet cell malignancies with related hormonal symptoms from glucagon, vasoactive intestinal peptide, insulin, and gastrin secretion. These tumors tend to follow a relatively indolent course and often become symptomatic only when the liver is involved with extensive metastatic disease. Consequently, many patients initially present with widespread liver involvement. Management of these tumors focuses on controlling tumor growth as well as managing symptoms related to tumor bulk and hormonal syndromes [79].

For patients with hormonally active disease, treatment typically focuses initially on controlling symptoms with medical therapy in the form of somatostatin analogs [80]. Some studies suggest somatostatin analogs may have an antiproliferative effect as well, thereby prolonging progression-free survival [81,82]. However, a significant percentage of patients either receive no clinical benefit from somatostatin analogs or become refractory to their therapeutic benefits over time [83].

With respect to managing tumor burden, resection of hepatic metastases can be beneficial in appropriate cases. In properly selected patients, resection confers a survival advantage over other treatment modalities [84,85]. Transplantation is uncommonly performed for neuroendocrine metastases [86]. Systemic therapy also has a limited role [87,88]. However, emerging data suggest that in certain subsets of neuroendocrine cancer, particularly pancreatic neuroendocrine tumors, systemic therapy options provide improved progression-free survival [89,90].

As with resection, thermal or chemical ablation may be feasible in certain cases; however, most patients present with multiple bilobar metastases, making ablation a suboptimal option for most patients [91]. Image-guided ablation, however, can still play a meaningful role as an adjunctive intraoperative therapy or as an alternative treatment for poor surgical candidates [92-94].

Due to the limited effectiveness or applicability of medical therapy and surgical/ablative techniques, arterial therapies often play a significant role in management. TAE and TACE have been shown to decrease hormonal symptoms and improve survival. Debate remains over which method of embolization is most effective, with some published studies arguing that bland hepatic artery embolization (TAE) produces essentially equivalent results as chemoembolization (TACE) [95-97]. As with treatment for other primary and secondary hepatic malignancies, there is also interest in treating metastatic neuroendocrine tumors with drug-eluting bead chemoembolization (DEB-TACE). This interest, however, has waned as there appears to be a higher rate of biloma formation when using DEB-TACE in this clinical setting [98,99]. There has also been increasing research into the use of SIRT in this patient population, with small studies suggesting therapeutic equivalency with more traditional arterial embolization techniques [100-102]. This finding was also reiterated in recent consensus guidelines from the European Neuroendocrine Tumor Society, in which it was found that insufficient evidence exists to determine which modality is superior with respect to treatment response and overall survival [103]. Moreover, recently published findings from a multidisciplinary expert working group suggest that, when compared with TAE and TACE, radioembolization patients experience fewer side effects from treatment and require fewer overall treatments [104,105].

Variants 6 and 7: Secondary hepatic malignancy; colorectal cancer, metastases to the liver

The gold standard in management of colon cancer metastatic to the liver remains resection [106]. Unfortunately, most patients are not candidates for surgery due to either disease bulk or the presence of extrahepatic metastases [107]. However, preoperative portal vein embolization can potentially increase the number of candidates for surgical resection [108-110]. Patients who are not eligible for resection may be potential candidates for palliative ablative or arterial interventions.

Ablation is most successful in patients with a limited number of smaller tumors [111]. Larger tumors can be treated with a combination of ablation and TAE or TACE. As with HCC, recent data have suggested that for properly selected patients, ablative techniques may approach equivalency with resection with respect to survival [112]. As with primary hepatic malignancy, early experience with SBRT also shows a potential role for this therapy for the treatment of liver metastases [113].

Arterial therapies such as TACE and SIRT, either as monotherapy or in combination with other therapeutic regimens, have also shown survival benefit [114,115]. As with HCC and metastatic neuroendocrine tumors, there continues to be a need for further research comparing the effectiveness of various locoregional treatment options as well as their use in conjunction with other treatments, including systemic therapy [116].

Primarily due to the development of more effective systemic therapy agents, HAI therapy has also been shown to be potentially beneficial for unresectable disease as well as in a neoadjuvant role [117]. However, this technique remains relatively unpopular due to the added cost and complexity of arterial pump placement as well as concerns over liver toxicity [118].

Summary of Recommendations

- Management of primary and secondary hepatic malignancy remains a complex issue due to the multitude of treatment options. For this reason, a multidisciplinary approach offers the best hope for optimal treatment with respect to any individual patient.
- Resection and transplantation remain the best options for cure in properly selected patients for primary malignancy as well as secondary malignancy in some limited scenarios; however, the role of RFA and potentially SBRT as primary treatment options are worthy of future research.
- SIRT is likely as effective as TACE or TAE for both primary and secondary hepatic malignancy and is often better tolerated.
- The choice between percutaneous ablative techniques and arterial methods will vary from institution to institution depending on operator expertise.
- Combining ablative and arterial treatments may yield better outcomes than arterial treatments alone.
- Due to the development and refinement of a wide range of therapies, particularly for secondary hepatic malignancies, protocols focusing on the proper combination and sequence of treatments may benefit from reexamination.

Summary of Evidence

Of the 118 references cited in the *ACR Appropriateness Criteria® Radiologic Management of Hepatic Malignancy* document, all of them are categorized as therapeutic references including 20 well designed studies, 45 good quality studies, and 3 quality studies that may have design limitations. There are 44 references that may not be useful as primary evidence. There are 6 references that are meta-analysis studies.

The 118 references cited in the *ACR Appropriateness Criteria® Radiologic Management of Hepatic Malignancy* document were published from 1996-2015

While there are references that report on studies with design limitations, 65 well designed or good quality studies provide good evidence.

Supporting Documents

For additional information on the Appropriateness Criteria methodology and other supporting documents go to www.acr.org/ac.

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The ACR Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the FDA have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.