附录 1

证据等级（牛津循证医学中心 2011 版）

（临床）问题	步骤 1	步骤 2	步骤 3	步骤 4	步骤 5
	（证据等级 1*）	（证据等级 2*）	（证据等级 3*）	（证据等级 4*）	（证据等级 5*）
这个疾病有多普遍?（患病率）	当地的,当前的随机样本调查（或普查）	与当地情况相匹配调查的系统综述**	当地的，非随机样本调查**	病例系列**	N/A
诊断或监测实验是否准确（诊断）	一致地应用了参考标准和盲法的横断面研究的系统综述	一致地应用了参考标准和盲法的横断面研究	非连续病例研究，或研究未能一致地应用参考标准**	病例对照研究，或应用了差的或非独立的参考标准**	基于机制的推理
若不给予这个治疗会发生什么?（预后）	起始队列研究的系统综述	起始队列研究	队列研究或随机研究的对照组*	病例系列或病例对照研究，或低质量预后队列研究**	N/A

这个治疗有用吗？（治疗效益）	随机试验或单病例随机对照试验的系统综述	随机试验或具有巨大效果的观察性研究	非随机对照队列/随访研究**	病例系列，病例对照研究，或历史对照研究**	基于机制的推理
这个治疗常见的伤害是什么（治疗伤害）	随机试验的系统综述，巢式病例对照研究的系统综述，针对你所提临床问题患者的 n-of-1 试验，具有巨大效果的观察性研究	单个随机试验或（特殊地）具有巨大效果的观察性研究	非随机对照队列/随访研究（上市后监测）提供，足够数量来排除常见的伤害（对长期伤害需要足够长的随访时间）**	病例系列，病例对照研究，或历史对照研究**	基于机制的推理
这个治疗少见的伤害是什么？（治疗伤害）	随机试验或 n-of-1 试验的系统综述	随机试验或（特殊地）具有巨大效果的观察性研究			
这个试验（早期发现）值得吗？（筛查）	随机研究的系统综述	随机试验	非随机对照队列/随访研究*	病例系列，病例对照研究，或历史对照研究**	基于机制的推理

注：* 根据研究质量、精确度、间接性，各个研究间不一致，若绝对效应值小，证据等级会被调低；若效应值很大，等级会被上调； **系统综述普遍地优于单项研究

附录 2

推荐强度

推荐强度	定义描述
强推荐	非常确信真实值接近效应估计值。基于：高质量研究证据支持净获益（例如，利大于弊）；研究结果一致性好，没有或很少有例外；对研究质量轻微或没有疑虑；和/或获得专家组成员的同意。其他基于高质量证据，确信利明显大于弊（包括指南的文献回顾和分析中讨论的内容）也可支持强推荐。
中等程度推荐	对效应估计值有中等程度信心。基于：较好研究证据支持净获益（例如，利大于弊）；研究结果一致，有轻微和/或少数例外；对研究质量轻微或少量疑虑；和/或获得专家组成员的同意。其他基于中等质量证据且利大于弊（包括指南的文献回顾和分析中讨论的内容）也可形成中度推荐。
弱推荐	对效应估计值信心有限，该推荐为临床实践提供了目前最好的指导。基于：有限的研究证据支持净获益（例如，利大于弊）；研究结果一致，但有重要的例外；研究质量有重要的疑虑；和/或获得专家组成员的同意。其他基于有限的证据（包括指南的文献回顾和分析中讨论的内容）也可导致弱推荐。

注：推荐强度“强推荐、中等程度推荐、弱推荐”正文中分别用“A、B、C”表示

附录 3

肝癌的液体活检

液体活检技术具有无创取样、多次检测、高度敏感等特性，常用标志物包括循环肿瘤细胞（circulating tumor cell，CTC）、循环游离 DNA（cell-free DNA，cfDNA），循环肿瘤 DNA（circulating tumor DNA，ctDNA）等，在肝癌的早期筛查及诊断、预后评估、疾病监测、疗效评估中展现出较高价值[432]。

CTC 检测可以成为一种肝癌预后预测和疗效评价的临床新工具[81,433]。有报道，外周血上皮细胞黏附分子阳性 CTC 具有干细胞样特性，是肝癌切除术后早期复发转移的独立预测指标[434]；检测 CTC 总体负荷、CTC 异质性亚型对肝癌患者经导管动脉化疗栓塞治疗后及放射治疗后肿瘤复发转移和进展具有预测作用[435, 436]；不同部位、不同时点检出的 CTC 能预测不同器官转移类型[437, 438]；术前 CTC 负荷可以指导外科手术切缘大小，降低复发转移可能[439]。此外，动态检测 CTC 可以用于监控肝癌肝移植术后肿瘤复发转移[440]。

cfDNA 是通过细胞凋亡、坏死和分泌释放到血液中的 DNA 物质。在癌症患者中，总 cfDNA 的主要成分是由肿瘤细胞释放的特异性突变 DNA 片段，即 ctDNA 组成，能够反映肿瘤的

遗传信息。据报道，ctDNA 用于肝癌早期诊断的灵敏度和特异度均优于血清甲胎蛋白[83, 441]，还可以动态反映肝癌手术切除效果[442, 443]、评估仑伐替尼、免疫检查点抑制剂治疗的疗效[444, 445]。有研究报道利用外周血低覆盖率全基因组 cfDNA 片段组学特征，可实现肝癌早期诊断和鉴别诊断，曲线下面积达 0.995，有望在临床推广应用[82]。

近期研究发现，利用特定基因表观遗传修饰特征，如甲基化[446]，5-hmc[84, 447]等也可以用于肝癌早期诊断。基于外周血 cfDNA 甲基化检测的 ELSA-seq 技术平台，所建立的 MCDBT-1 模型可以用于癌症溯源和肝癌早期筛查，显著优于其他癌种[448]。也有研究报道，通过对 cfDNA 的体细胞突变和甲基化特征的多重同步分析，相互补充，可以更为有效地发现早期肝癌[449]。

此外，其他新型液体活检标志物如血清自身抗体[450]，血浆代谢物[451]、肿瘤相关血小板[452]、循环 T 细胞受体库[453]、外周血免疫细胞亚群检测[454]等在肝癌早期诊断、疗效监测中也表现出一定潜力。

附录 4

推荐肝癌病理诊断报告及主要描述指标

<table>
<tr><td>请临床协助填写：
肿瘤部位及术式：肝叶切除/肝段切除/局部切除/其他：
术前治疗：无/有，介入/消融/靶向/免疫检查点抑制剂/其他：</td><td>肿瘤数量（n= ）；肿瘤大小：（多结节性肿瘤应尽可能逐一测量 cm× cm× cm）
肿瘤取材方式：“7 点”取材；其他：</td></tr>
<tr><td>大体类型：
肝细胞癌：单结节型有包膜/单结节型无包膜、多结节型、巨块型、弥漫型、其他：
肝内胆管癌：管周浸润型、肿块型、混合型、其他：
坏死：无/有（具体比例）</td><td>组织学类型：
肝细胞癌：细梁型、粗梁型、假腺管型、团片型
特殊亚型：双表型、纤维板层型、硬化型、透明细胞型、富脂型、嫌色型、富中性粒细胞型、富淋巴细胞型和未分化型、其他：
肝内胆管癌：大胆管型、小胆管型、细胆管癌、胆管板畸形型
特殊亚型：腺鳞癌、淋巴上皮瘤样型、肉瘤样型、其他：
混合型肝细胞癌-胆管癌（分别描述两种肿瘤成分的比例）</td></tr>
<tr><td>分化分级：
肝细胞癌（I、II、III、IV/高、中、低）
肝内胆管癌（高、中、低）</td><td>卫星灶：无/有
MVI：无/有
血管内松散悬浮癌细胞：无/有</td></tr>
<tr><td>大血管癌栓（巨检/手术所见）：无/有
大血管癌栓位置（根据临床信息）：</td><td>大胆管癌栓（巨检/手术所见）：无/有
小胆管癌栓（显微镜下所见）：无/有</td></tr>
<tr><td colspan="2">MVI 病理分级：
M0：未发现 MVI；
M1（低危组）：≤5 个 MVI，均发生于近癌旁肝组织（≤1cm）；
M2a（高危组）：＞5 个 MVI，均发生于近癌旁肝组织（≤1cm）；</td></tr>
</table>

M2b（高危组）：MVI 发生于远癌旁肝组织（＞1cm）。	
肝细胞异型增生结节：无/有，低级别/高级别 肝硬化：无/有，小结节/大结节/混合结节型	胆管上皮内瘤变：无/有，低级别/高级别 胆管内乳头状肿瘤：无/有，低级别/高级别
切缘：无癌，距肿瘤最近距离 cm	肝被膜：未侵犯/侵犯
癌周围肝组织： 肝细胞异型增生：无/肝细胞大、小细胞变 脂肪变程度：无、轻度、中度、重度 肝炎：无/有，肝炎程度 G，纤维化分期 S	周围神经侵犯：无/有 淋巴结/远处转移：无/有，部位：
胆囊侵犯：无/有	膈肌侵犯：无/有
转化治疗/新辅助治疗后切除肝癌标本的病理学评估：pCR、MPR 百分比：	免疫检查点抑制剂治疗后癌旁肝组织免疫相关肝损伤：无/有，肝细胞损伤、小叶内肝炎、胆管炎

注：MVI 为微血管侵犯；**pCR** 为病理学完全缓解；**MPR** 为明显病理学缓解。

附录 5

经动脉介入治疗进展

1. 肝动脉灌注化疗（hepatic artery infusion chemotherapy，HAIC）：作为一种动脉内灌注化疗的介入治疗方式，HAIC 目前尚未形成统一治疗技术标准，疗效差异较大。日本多中心、随机对照Ⅱ期临床试验研究（SCOOP-2 试验）对比顺铂 HAIC 序贯索拉非尼与标准索拉非尼单药治疗晚期肝癌患者，结果显示 HAIC 联合治疗组的中位生存期为 10 个月，对比索拉非尼单药治疗组的 15.2 个月，疗效不理想。HAIC 联合治疗组中有 23%的患者由于一般状况恶化而无法在 HAIC 后接受任何进一步的治疗[455]。多中心随机III期试验（SILIUS 试验）除证实了该前瞻性随机Ⅱ期试验的阴性结果外，还测试了不同的 HAIC 方案（低剂量顺铂-氟尿嘧啶）联合索拉非尼对比索拉非尼单药治疗日本晚期肝癌患者，同样为阴性结果[456]。目前，日本将 HAIC 推荐为 TACE 失败/抵抗后肝功能 Child-Pugh A 级，且靶向药物等系统抗肿瘤进展的肝癌患者或肝功能 Child-Pugh B 级晚期肝癌患者的治疗方式[457]（证据等级 2，推荐 B）。近年来我国学者采用 mFOLFOX 为基础的灌注方案使晚期肝癌患者 HAIC 疗效得以提高。目前普遍认为经导管动脉化疗栓塞（transcatheter

arterial chemoembolization，TACE）疗效优于 HAIC，但有一项针对不伴血管浸润或肝外转移的不可切除大肝癌患者的随机对照研究显示 mFOLFOX-HAIC 疗效优于 TACE[458]。与 TACE 类似，mFOLFOX-HAIC 对部分肿瘤最大径＞7cm，初始不适合外科手术切除的肝癌患者，有助于转化，但一般建议连续完成 4 次或以上的 HAIC 治疗才能达到转化治疗的机会。2023 年，我国学者发表了肝癌 mFOLFOX-HAIC 中国专家共识，为 HAIC 治疗提供了规范化指引和推荐[459]。

2. TACE 预后的术前预测模型

（1）“Six-and-twelve”模型：即将肿瘤大小+数量之和分为≤6，＞ 6 且≤12，＞12 三组。该模型对接受 TACE 治疗的肝癌患者进行个体化预后评估和危险分层，患者的风险分层不同，其中位生存时间差异显著。因此，使用“Six-and-twelve”模型，能为肝癌患者 TACE 术前提供术后预期生存的参考值，辅助患者选择不同的治疗方式[306]（证据等级 2，推荐 B）。

（2）TACE 的预后列线图模型：包含门静脉侵犯、肿瘤数目、肿瘤包膜、血清甲胎蛋白（alpha-fetoprotein，AFP）、谷草转氨酶、吲哚菁绿 15 min 滞留率等因素。该模型经 868 例肝癌患者验证，其预测生存相关的 C-指数达 0.755[460]。因此，使用上述两种模型能为肝癌患者 TACE 术前提供术后预

期生存的参考值，辅助患者选择不同的治疗方式。

（3）“TACE-predict”模型：是针对肝癌 TACE 人群，可以在术前应用并在术后再次校准的个体化预后评估和危险分层模型。研究发现，肿瘤数目与直径、AFP、白蛋白、胆红素、血管侵犯、病因是 TACE 术前患者的预后因素；肿瘤数目与直径、AFP、胆红素、血管侵犯及影像学应答是 TACE 术后患者的预后因素。据此建立了 Pre-TACE-Predict 模型和 Post-TACE-Predict 模型，该模型可分别在 TACE 术前和术后计算患者生存概率。Pre-TACE-Predict 模型和 Post-TACE-Predict 模型的预测能力优于 HAP 和 mHAP Ⅲ评分。Post-TACE-Predict 模型能够在术后对患者进行进一步预后评估和危险分层，并有助于辅助 TACE 后续的治疗决策，对指导临床实践具有重大意义（证据等级 2，推荐 B）[461]。

3. TACE/HAIC 联合分子靶向、免疫检查点抑制剂治疗：TACTICS Ⅱ期研究表明，TACE 联合索拉非尼较单一 TACE 明显改善不可手术切除 BCLC A/B 期肝癌患者的无进展生存时间（25.2 个月 *vs* .13.5 个月；*P*=0.02，风险比 0.59），但总生存时间差异无统计学意义（36.2 个月 *vs.* 30.8 个月；*P*=0.40）[462]。STAH 研究表明，对于 BCLC C 期的肝癌患者，TACE 联合索拉非尼较单一索拉非尼无生存获益（12.8 个月 *vs.* 10.8 个月；风险比 0.91）[463]。LAUNCH 研究表明，TACE

联合仑伐替尼较单一仑伐替尼可明显提高晚期肝癌患者的客观缓解率（54.1% *vs.* 25%）、无进展生存时间（10.6 个月 *vs.* 6.4 个月；风险比 0.43）和总生存时间（17.8 个月 *vs.* 11.5 个月；风险比 0.45）[184]。DEB-TACE 联合仑伐替尼较单一仑伐替尼的真实世界、多中心、回顾性研究显示，联合治疗能明显提高不可手术切除肝癌患者的客观缓解率（46.5% *vs.* 13.1%)和总生存时间(15.9 个月 *vs.* 8.6 个月;*P*=0.002）[308]。在一线标准系统抗肿瘤治疗耐药后，TACE 联合瑞戈非尼二线治疗的单臂、真实世界研究显示可延长中晚期肝癌患者无进展生存时间至 9.1 个月及总生存时间至 14.3 个月[464]，回顾性对照研究也显示 TACE 联合瑞戈非尼较单一瑞戈非尼延长晚期肝癌患者的总生存时间（11.3 个月 *vs.* 8.2 个月；*P*=0.034）[465]。 CHANCE001 是目前国内 TACE 联合靶向及免疫治疗肝癌样本量最大的多中心真实世界研究，证实联合治疗较单纯 TACE 治疗显著改善中晚期肝癌患者的无进展生存时间（9.5 个月 *vs.* 8.0 个月，风险比 0.70）与总生存时间（19.2 个月 *vs.* 15.7 个月,风险比 0.63)[309]。CHANCE2211[310]是 TACE 联合卡瑞利珠单克隆抗体和阿帕替尼治疗 BCLC B/C 期肝癌的全国多中心、回顾性队列研究，研究结果显示联合治疗组的中位总生存时间、无进展生存时间和客观缓解率显著优于单纯 TACE 治疗组（中位总生存时间：24.1 个月 *vs.*

15.7 个月，风险比 0.41；中位无进展生存时间：13.5 个月 *vs.* 7.7 个月 风险比 0.52；客观缓解率，59.5% *vs.* 37.4%)。目前，多项 TACE/HAIC 联合系统抗肿瘤治疗的III期临床研究正在进行中。

附录 6

TARE 治疗进展

TARE 是指采用经皮穿刺将导管插管至肿瘤供血动脉内，注射带有放射性核素的物质，通过放射性核素在肿瘤局部聚集和持续内照射毁损并杀灭肿瘤，从而达到控制肿瘤生长的治疗方法。TARE 属内放射范畴，也称为选择性内放射治疗（selective internal radiation therapy，SIRT）[466]。与 TACE 主要通过化疗药物细胞毒作用和肿瘤动脉分支栓塞使肿瘤缺血坏死不同，TARE 主要通过放射性核素释放高能量射线（β 射线）持续近距离照射使肿瘤组织坏死。同时，放射性微球直径较小（20～60 μm），血管栓塞作用较 TACE 轻微[466]。

TARE 最常用的放射性微球为钇-90（^{90}Y）微球。根据载体不同，^{90}Y 微球分为玻璃微球（TheraSphere）和树脂微球（SIR-Sphere）两种[467]。TheraSphere 和 SIR-Sphere 分别于 1999 年和 2002 年获得美国 FDA 批准用于肝脏恶性肿瘤的 TARE 治疗，其中 TheraSphere 的适应证为治疗不可切除的肝癌，SIR-Sphere 的适应证为联合氟脲苷动脉化疗治疗不可手术切除的结直肠癌肝转移。这两种微球在临床实际应用中互有交互。在欧洲、亚洲部分国家和地区还被批准用于治疗其他不能手术切除的肝脏恶性肿瘤，如胆管细胞癌、神经内分

泌肿瘤肝转移等[468]。

TARE 治疗需要由介入放射科、肝脏外科、核医学科、放射肿瘤科和肿瘤内科等组成的多学科团队共同完成。根据患者一般状况、肝功能状况、肿瘤分期、治疗目的等情况以及肝-肺分流等因素制定治疗计划和计算放射性计量[467,469]。

肝癌患者 TARE 的临床应用主要包括[470-473]:①早期肝癌患者的根治性治疗，可使肿瘤完全坏死；②中期肝癌患者的降期治疗，为外科手术切除或肝移植创造条件；③晚期肝癌患者（伴门静脉癌栓）的姑息性治疗，延长患者生存期；④放射性肝段/肝叶切除，治疗肿瘤的同时使余肝体积增加，为外科手术切除创造机会；⑤与系统抗肿瘤治疗联合，提高肝癌患者疗效。

尽管 TARE 是肝癌患者有效的血管内介入治疗方法，已经在国外临床应用了 20 余年，但国内目前仍未获批用于原发性肝癌患者的治疗，也缺乏中国肝癌患者 TARE 的数据。期待 ^{90}Y 微球的获批和临床应用，为我国肝癌患者增加新的治疗方法。

附录 7

肝癌外放射治疗正常组织具体耐受剂量参考

1.立体定向放射治疗：①肝功能Child-Pugh A级，放射治疗分次数3～5Fx，正常肝体积[肝脏体积-大体肿瘤体积，Liver-Gross tumor volume（GTV）]＞700ml或＞800ml，Liver-GTV平均剂量分别＜15Gy或＜18Gy；放射治疗分次数6Fx，Liver-GTV体积＞800ml，平均剂量＜20Gy；每次肿瘤分割剂量4～8Gy，Liver-GTV平均剂量＜23Gy为安全剂量（证据等级3，推荐B）[474,475]。②亚洲肝癌患者常伴有肝硬化和脾功能亢进，导致胃肠道淤血和凝血功能差，胃肠道的放射耐受剂量低于RTOG推荐的剂量[476]；目前文献及专家共识认为，放射治疗分次数3～5Fx，胃和小肠最大剂量均应＜22.2～35Gy，最佳＜30Gy。③放射治疗分次数3～5Fx，双肾平均剂量最佳＜10Gy，脊髓最大剂量＜21.9～30Gy，最佳＜18～23Gy[477]。

2.常规分割剂量放射治疗：①肝功能 Child-Pugh A级，Liver-GTV 平均剂量＜28～30Gy；肝功能 Child-Pugh B 级者，肝脏对射线的耐受量明显下降，最佳＜6Gy，避

免肝功能 Child-Pugh C 级患者行肝区放射治疗[295,475]。②胃和小肠最大剂量均应＜54Gy，胃 V_{45}＜45%，小肠 V_{50}≤5%。③双肾平均剂量≤15Gy，如一侧肾脏平均剂量大于 19Gy，则另一侧肾脏尽量避开；脊髓最大剂量＜45Gy[474]。

附录 8

《原发性肝癌诊疗指南（2024 年版）》编写专家委员会

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