



National Comprehensive
Cancer Network®

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

Hepatobiliary Cancers

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NCCN.org



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肝胆癌分期 (ST-1,2,3,4,5)

ST-1 肝细胞癌 TNM 分期

ST-2 胆囊癌 TNM 分期

表 2
美国癌症联合会(AJCC)
胆囊癌 TNM 分期 (第8版, 2017)

原发肿瘤 (T)

- TX** 原发肿瘤不能评价
- T0** 无原发肿瘤证据
- Tis** 原位癌
- T1** 肿瘤侵犯固有层或肌层
- T1a** 肿瘤侵犯固有层
- T1b** 肿瘤侵犯肌层
- T2** 肿瘤侵犯腹膜侧的肌层旁结缔组织, 而不累及浆膜(脏层腹膜)或肿瘤侵犯肝侧的肌层旁结缔组织, 但没有侵入肝脏
- T2a** 肿瘤侵犯腹膜侧的肌层旁结缔组织, 而不累及浆膜(脏层腹膜)
- T2b** 肿瘤侵犯肝侧的肌层旁结缔组织, 但没有侵入肝脏
- T3** 肿瘤穿透浆膜(脏层腹膜)和/或 直接侵犯肝脏 和/或 一个其它临近器官或结构,例如胃、十二指肠、结肠、胰腺、网膜或肝外胆管
- T4** 肿瘤侵犯门静脉主干或肝动脉或侵犯2个或2个以上肝外器官或结构

局部淋巴结 (N)

- NX** 局部淋巴结不能评价
- N0** 无局部淋巴结转移
- N1** 1-3个局部淋巴结转移
- N2** 4个或4个以上局部淋巴结转移

远处转移 (M)

- M0** 无远处转移
- M1** 远处转移

解剖分期/预后分组 期

0 期	Tis	N0	M0
I 期	T1	N0	M0
IIA 期	T2a	N0	M0
IIB 期	T2b	N0	M0
IIIA 期	T3	N0	M0
IIIB 期	T1-3	N1	M0
IVA 期	T4	N0-1	M0
IVB 期	任何 T	N2	M0
	任何 T	任何 N	M1

组织学分级 (G)

- GX** 分级不能评价
- G1** 高分化
- G2** 中分化
- G3** 低分化



Table 2
American Joint Committee on Cancer (AJCC)
TNM Staging for Gallbladder Carcinoma (8th ed., 2017)

Primary Tumor (T)

- TX** Primary tumor cannot be assessed
- T0** No evidence of primary tumor
- Tis** Carcinoma *in situ*
- T1** Tumor invades lamina propria or muscular layer
- T1a** Tumor invades lamina propria
- T1b** Tumor invades muscle layer
- T2** Tumor invades the perimuscular connective tissue on the peritoneal side, without involvement of the serosa (visceral peritoneum) Or tumor invades the perimuscular connective tissue on the hepatic side, with no extension into the liver
- T2a** Tumor invades the perimuscular connective tissue on the peritoneal side, without involvement of the serosa (visceral peritoneum)
- T2b** Tumor invades the perimuscular connective tissue on the hepatic side, with no extension into the liver
- T3** Tumor perforates the serosa (visceral peritoneum) and/or directly invades the liver and/or one other adjacent organ or structure, such as the stomach, duodenum, colon, pancreas, omentum, or extrahepatic bile ducts
- T4** Tumor invades main portal vein or hepatic artery or invades two or more extrahepatic organs or structures

Regional Lymph Nodes (N)

- NX** Regional lymph nodes cannot be assessed
- N0** No regional lymph node metastasis
- N1** Metastases to one to three regional lymph nodes
- N2** Metastases to four or more regional lymph nodes

Distant Metastasis (M)

- M0** No distant metastasis
- M1** Distant metastasis

Anatomic Stage/Prognostic Groups

Stage 0	Tis	N0	M0
Stage I	T1	N0	M0
Stage IIA	T2a	N0	M0
IIB	T2b	N0	M0
Stage IIIA	T3	N0	M0
IIIB	T1-3	N1	M0
Stage IVA	T4	N0-1	M0
IVB	Any T	N2	M0
	Any T	Any N	M1

Histologic Grade (G)

- GX** Grade cannot be assessed
- G1** Well differentiated
- G2** Moderately differentiated
- G3** Poorly differentiated



ST-3 肝内胆管癌 TNM 分期

表 3
美国癌症联合会(AJCC)
肝内胆管癌 TNM 分期 (第8版, 2017)

原发肿瘤 (T)

TX	原发肿瘤不能评价
T0	无原发肿瘤证据
Tis	原位癌 (胆管内肿瘤)
T1	单发肿瘤但无血管侵犯, ≤5 cm 或 >5 cm
T1a	单发肿瘤 ≤5 cm 但无血管侵犯
T1b	单发肿瘤 >5 cm 但无血管侵犯
T2	单发肿瘤伴肝内血管侵犯或多发肿瘤, 有或无血管侵犯
T3	肿瘤穿透脏层腹膜
T4	肿瘤通过直接侵犯累及局部肝外结构

局部淋巴结 (N)

NX	局部淋巴结无法评价
N0	无局部淋巴结转移
N1	有局部淋巴结转移

远处转移 (M)

M0	无远处转移
M1	有远处转移

解剖分期/预后分组

0 期	Tis	N0	M0
IA 期	T1a	N0	M0
IB 期	T1b	N0	M0
II 期	T2	N0	M0
IIIA 期	T3	N0	M0
IIIB 期	T4	N0	M0
IIIB 期	任何 T	N1	M0
IV 期	任何 T	任何 N	M1

组织学分级 (G)

GX	分级不能评价
G1	高分化
G2	中分化
G3	低分化


 指南解读

Table 3
American Joint Committee on Cancer (AJCC)
TNM Staging for Intrahepatic Bile Duct Tumors (8th ed., 2017)

Primary Tumor (T)

TX	Primary tumor cannot be assessed
T0	No evidence of primary tumor
Tis	Carcinoma <i>in situ</i> (intraductal tumor)
T1	Solitary tumor without vascular invasion, ≤5 cm or >5 cm
T1a	Solitary tumor ≤5 cm without vascular invasion
T1b	Solitary tumor >5 cm without vascular invasion
T2	Solitary tumor with intrahepatic vascular invasion or multiple tumors, with or without vascular invasion
T3	Tumor perforating the visceral peritoneum
T4	Tumor involving local extrahepatic structures by direct invasion

Regional Lymph Nodes (N)

NX	Regional lymph nodes cannot be assessed
N0	No regional lymph node metastasis
N1	Regional lymph node metastasis present

Distant Metastasis (M)

M0	No distant metastasis
M1	Distant metastasis present

Anatomic Stage/Prognostic Groups

Stage 0	Tis	N0	M0
Stage IA	T1a	N0	M0
IB	T1b	N0	M0
Stage II	T2	N0	M0
Stage IIIA	T3	N0	M0
IIIB	T4	N0	M0
IIIB	Any T	N1	M0
Stage IV	Any T	Any N	M1

Histologic Grade (G)

GX	Grade cannot be assessed
G1	Well differentiated
G2	Moderately differentiated
G3	Poorly differentiated

 指南解读

ST-4 肝门胆管肿瘤 TNM 分期

表 4
美国癌症联合会(AJCC)
肝门胆管肿瘤 TNM 分期 (第8版, 2017)

原发肿瘤 (T)

TX	原发肿瘤不能评价
T0	无原发肿瘤证据
Tis	原位癌/重度不典型增生
T1	肿瘤局限于胆管, 累及至肌层或纤维组织
T2	肿瘤侵犯超出胆管壁达周围脂肪组织, 或肿瘤侵犯临近肝实质
T2a	肿瘤侵犯超出胆管壁达周围脂肪组织,
T2b	肿瘤侵犯临近肝实质
T3	肿瘤侵犯门静脉某一支或肝动脉
T4	肿瘤侵犯门静脉主干或双侧分支, 或肝总动脉; 或双侧二级胆管; 或单侧二级胆管伴对侧门静脉或肝动脉受累

局部淋巴结 (N)

NX	局部淋巴结不能评价
N0	无局部淋巴结转移
N1	1-3个淋巴结转移, 通常累及肝门、胆囊管、胆总管、肝动脉、胰十二指肠和门静脉淋巴结
N2	4个或4个以上来自上述N1描述部位的淋巴结

远处转移 (M)

M0	无远处转移
M1	有远处转移

解剖分期/预后分组

0 期	Tis	N0	M0
I 期	T1	N0	M0
II 期	T2a-b	N0	M0
IIIA 期	T3	N0	M0
IIIB	T4	N0	M0
IIIC	任何 T	N1	M0
IVA 期	任何 T	N2	M0
IVB	任何 T	任何 N	M1

组织学分级 (G)

GX	分级不能评价
G1	高分化
G2	中分化
G3	低分化

 指南解读

Table 4

American Joint Committee on Cancer (AJCC)
TNM Staging for Perihilar Bile Duct Tumors (8th ed., 2017)

Primary Tumor (T)

TX	Primary tumor cannot be assessed
T0	No evidence of primary tumor
Tis	Carcinoma <i>in situ</i> /high-grade dysplasia
T1	Tumor confined to the bile duct, with extension up to the muscle layer or fibrous tissue
T2	Tumor invades beyond the wall of the bile duct to surrounding adipose tissue, or tumor invades adjacent hepatic parenchyma
T2a	Tumor invades beyond the wall of the bile duct to surrounding adipose tissue
T2b	Tumor invades adjacent hepatic parenchyma
T3	Tumor invades unilateral branches of the portal vein or hepatic artery
T4	Tumor invades main portal vein or its branches bilaterally, or the common hepatic artery; or unilateral second-order biliary radicals bilaterally with contralateral portal vein or hepatic artery involvement

Regional Lymph Nodes (N)

NX	Regional lymph nodes cannot be assessed
N0	No regional lymph node metastasis
N1	One to three positive lymph nodes typically involving the hilar, cystic duct, common bile duct, hepatic artery, posterior pancreaticoduodenal, and portal vein lymph nodes
N2	Four or more positive lymph nodes from the sites described for N1

Distant Metastasis (M)


M0	No distant metastasis
M1	Distant metastasis

Anatomic Stage/Prognostic Groups

Stage 0	Tis	N0	M0
Stage I	T1	N0	M0
Stage II	T2a-b	N0	M0
Stage IIIA	T3	N0	M0
IIIB	T4	N0	M0
IIIC	Any T	N1	M0
Stage IVA	Any T	N2	M0
IVB	Any T	Any N	M1

Histologic Grade (G)

GX	Grade cannot be assessed
G1	Well differentiated
G2	Moderately differentiated
G3	Poorly differentiated

 指南解读

ST-5 远端胆管肿瘤 TNM 分期

表 5
美国癌症联合会(AJCC)
远端胆管肿瘤 TNM 分期 (第8版, 2017)

无原发肿瘤 (T)

- TX** 原发肿瘤不能评价
Tis 原位癌/重度不典型增生
T1 肿瘤侵犯胆管壁, 侵犯深度不超过 5 mm
T2 肿瘤侵犯胆管壁, 侵犯深度为5–12 mm
T3 肿瘤侵犯胆管壁, 侵犯深度超过12mm
T4 肿瘤侵犯腹腔干、肠系膜上动脉、和/或肝总动脉

局部淋巴结 (N)

- NX** 局部淋巴结无法评价
N0 无局部淋巴结转移
N1 1-3个局部淋巴结转移
N2 4个或4个以上局部淋巴结转移

远处转移 (M)

- M0** 无远处转移
M1 有远处转移

解剖分期/预后分组

0 期	Tis	N0	M0
I 期	T1	N0	M0
IIA期	T1	N1	M0
	T2	N0	M0
IIB期	T2	N1	M0
	T3	N0	M0
	T3	N1	M0
IIIA期	T1	N2	M0
	T2	N2	M0
	T3	N2	M0
IIIB期	T4	N0	M0
	T4	N1	M0
	T4	N2	M0
IV 期	任何 T	任何 N	M1

组织学分级 (G)

- GX** 分级不能评价
G1 高分化
G2 中分化
G3 低分化



Table 5

American Joint Committee on Cancer (AJCC)
 TNM Staging for Distal Bile Ducts Tumors (8th ed., 2017)

Primary Tumor (T)

- TX** Primary tumor cannot be assessed
Tis Carcinoma in situ/high-grade dysplasia
T1 Tumor invades the bile duct wall with a depth less than 5 mm
T2 Tumor invades the bile duct wall with a depth of 5–12 mm
T3 Tumor invades the bile duct wall with a depth greater than 12 mm
T4 Tumor involves the celiac axis, superior mesenteric artery, and/or common hepatic artery

Regional Lymph Nodes (N)

- NX** Regional lymph nodes cannot be assessed
N0 No regional lymph node metastasis
N1 Metastasis in one to three regional lymph nodes
N2 Metastasis in four or more regional lymph nodes

Distant Metastasis (M)

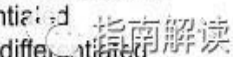
- M0** No distant metastasis
M1 Distant metastasis

Anatomic Stage/Prognostic Groups

Stage 0	Tis	N0	M0
Stage I	T1	N0	M0
Stage IIA	T1	N1	M0
	T2	N0	M0
Stage IIB	T2	N1	M0
	T3	N0	M0
	T3	N1	M0
Stage IIIA	T1	N2	M0
	T2	N2	M0
	T3	N2	M0
Stage IIIB	T4	N0	M0
	T4	N1	M0
	T4	N2	M0
Stage IV	Any T	Any N	M1

Histologic Grade (G)

- GX** Grade cannot be assessed
G1 Well differentiated
G2 Moderately differentiated
G3 Poorly differentiated



更新内容

2018 年 12 月 17 日，美国国立综合癌症网络更新了《NCCN 肝胆癌临床实践指南》，具体更新内容如下：

肝细胞肝癌

1. 影像学检查原则

● 肝细胞癌的主要影像学特征，作了修改：

- ▶ 旧版：包括动脉期显著强化、静脉期或延迟期减退、被膜表现以及阈值增长
- ▶ 新版：包括动脉期显著强化、**非外周区域**静脉期或延迟期减退、被膜表现**强化**以及阈值增长

2. 手术原则

● 新增了 1 条：

- ▶ 基于回顾性分析的结果，老年患者可能从肝切除或 HCC 移植中受益，但需要进行仔细筛选，因为其总生存期不如年轻患者。

3. 局部治疗原则

● 局部治疗的大体分类作了修改：

- ▶ 旧版：“消融、动脉介入治疗”二分类
 - ▶ 新版：“消融、动脉介入治疗、**放疗**”三分类
-

胆囊癌

1. 检查

● 对于无法切除和远处转移的胆囊癌患者，推荐检测的免疫治疗预后相关指标，在原来微卫星不稳定（MSI）的基础上，**新增了错配修复（MMR）**。

2. 治疗

● 对于局部晚期胆囊癌的新辅助治疗，新增了一点说明：目前可用于确定标准方案或明确获益的临床试验数据有限。

● 帕博利珠单抗用于治疗无法切除或远处转移胆囊癌患者的适用人群，作了修改：▶ 旧版：仅适用于 MSI-H 的肿瘤

- ▶ 新版：仅适用于 MSI-H/dMMR 的肿瘤
-

肝内胆管癌

治疗

● 支持用于无法切除或转移性肝内胆管癌的联合治疗方案，新增了 1 个选择：**吉西他滨/白蛋白结合型紫杉醇**。

● 删除了 1 个支持用于肝内胆管癌术后的辅助化疗方案：

- ▶ ~~吉西他滨/奥沙利铂~~
-

肝外胆管癌

治疗

● 新增了 1 条：

▶ 对于无法切除的肝门周围或肝门部胆管癌，如果径向测量直径 $\leq 3\text{cm}$ ，无肝内或肝外转移且无淋巴结转移，可考虑在 UNOS 批准可开展胆管癌移植手术的移植中心进行肝移植。

● 删除了 2 个支持用于无法切除或转移性肝外胆管癌的化疗方案：

- ▶ ~~“吉西他滨/奥沙利铂”联合方案~~
- ▶ ~~“吉西他滨”单药方案。~~