高 雄 榮 民 總 醫 院
胰臟癌診療指引

2021年04月20日 第一版

胰臟癌醫療團隊擬訂

注意事項：這個診療原則主要作為醫師和其他保健專家診療癌症病人參考之用。假如你是一個癌症病人，直接引用這個診療原則並不恰當，只有你的醫師才能決定給你最恰當的治療。

會議討論

上次會議：2020/07/21(第二版)

本共識與上一版的差異

上一版	新版
1.「Resectable」、「Borderline resectable」、「Locally advanced」跟「Metastatic」評估項目。 2.「Resectable」治療部分。 3.「Borderline resectsble」診斷內容。 4.「Borderline resectsble」治療內容。 5.膽道阻塞、黃疸症狀處置內容。 6.新輔助化療regimen。 7.動脈內化學放射治療處方。	1-1. 新增胸部電腦斷層攝影。 (P.3~P.5) 1-2. 腫瘤指標CA 19-9建議"after bile duct drainage"後抽，以建立baseline資料。(P.3~P.5) 1-3. 內視鏡超音波+FNA，新增FNB。(P.3~P.5) 2.「Resectable」治療:EUS-guide biopsy新增"& Consider stent"。(P.3) 3.刪除"針對轉移性病灶切片"敘述；條列式分類切片方式，新增"2.staging laparoscopy"、EUS-FNA新增"FNB"。 (P.4) 4.建議Biopsy positive / Neoadjuvant 前要 DRAINAGE。(P.4) 5.刪除"PTCD or PTGBD"敘述。(P.3~P.5) 6.新增"mFOLFIRINOX"regimen。(P.9) 7. 修改動脈內化學放射治療處方。(P.14)

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評估	診斷	治療	追蹤

評估

- 病史，理學檢查
- 營養及日常體能狀態
- 胸部X光#
- 血液常規
- 電解質及肝腎功能
- 腫瘤指標 (CEA, Ca19-9)- after bile duct drainage
- 腹部超音波#
- 胸部電腦斷層攝影
- 腹部電腦斷層攝影 *
- 核磁共振檢查(MRI)*
- 正子攝影檢查(PET)*
- 內視鏡超音波＋FNA/FNB
- 經內視鏡逆行性膽胰管攝影術（ERCP）
- 必要時腹腔鏡評估

*與癌症期別相關之主要檢查(擇一)
#與癌症期別相關之次要檢查

診斷 / 治療

Resectable

→ 剖腹手術或腹腔鏡手術切除
- R0,LN(-) → ± Adjuvant C/T
- R0,LN(+)
  - ECOG≦2 → Adjuvant C/T
  - ECOG＞2 → 支持性治療
- R1,R2
  - ECOG≦2 → Adjuvant C/T或CCRT＋C/T(比照局部晚期)
  - ECOG＞2 → 支持性治療
- 術中發現不可切除 → 切片±繞道手術 (Biliary ± GI bypass) → C/T或CCRT＋C/T或IA（比照局部晚期）

→ **EUS-guide biopsy** & Consider stent → **Neoadjuvant C/T** (Particularly in high-risk patients) → 評估手術時機

膽道阻塞 Resectable	Unresectable
*術前膽管炎→塑膠架或體外引流 *術前黃疸但無膽管炎→不需引流	術前膽管炎、黃疸→塑膠支架、金屬支架、體外引流

追蹤

※ **GOT/GPT, ALP, Alb, CBC, CEA, CA199 , Abdominal CT or MRI Every 3 months for 2 years Every 6 months for 3-5years then annually**
※ **CXR Every 6 months for 5 years then annually**

High-risk features include imaging findings, very highly elevated CA 19-9, large primary tumors, large regional lymph nodes, excessive weight loss, extreme pain.

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•腹部電腦斷層攝影 *
•核磁共振檢查(MRI)*
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Borderline Resectable

1.CT-guide
~~2.staging laparoscopy~~
3.exploratory LAPA切片
4.EUS+FNA/FNB

Cancer not confirmed → Repeat biopsy → Biopsy Positive

Biopsy Positive → **Neoadjuvant therapy**

評估手術可能性

- Surgical resection → See **Resectable** Treatment
- Unresectable at surgery → See **Unresectable/ Locally advanced** Treatment
- Disease progression → See **Locally advanced/ Metastatic Disease** Treatment

•Neoadjuvant 前要 DRAINAGE
•如有黃疸症狀:金屬支架、塑膠支架、體外引流

※
GOT/GPT, ALP, Alb, CBC, CEA, CA199, Every 6 months Abdominal CT or MRI Every 3 months for 2 years for 3-5years then annually
※ CXR Every 6 months for 5 years then annually

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Unresectable Locally advanced

Metastatic Disease

日常體能狀態(ECOG)

ECOG≦0-2 → CT-guide/ Exploratory LAPA切片 或 EUS+FNA/FNB 或可針對轉移病灶切片 → C/T 或 CCRT＋C/T或支持性治療或臨床試驗

ECOG＞2分 → 支持性治療

如有黃疸症狀
- ●金屬支架
- ●塑膠支架
- ●體外引流

※ GOT/GPT, ALP, Alb, CBC, CEA, CA199 , Abdominal CT or MRI Every 3 months for 2 years Every 6 months for 3-5years then annually
※ CXR Every 6 months for 5 years then annually

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Criteria defining resectability status at diagnosis

Reference (No): 1

＊可手術切除 (MD-CT or MRI)：
① 無遠處轉移
② 上腸繫膜靜脈(SMV)或肝門靜脈(PV)完好
③ 腹腔動脈幹(celiac trunk)、肝動脈(HA)、上腸繫膜動脈(SMA)完好
＊**Borderline**可切除：
① 無遠處轉移
② 上腸繫膜靜脈(SMV)或肝門靜脈(PV)可能被侵犯，但可手術切除部份血管並清除腫瘤
③ 胃十二指腸動脈(GDA)或肝動脈(HA)被侵犯，但可手術切除部份血管並清除腫瘤
④ 上腸繫膜動脈(SMA)完好，但未超過180°
＊ 不可切除：
胰臟頭部腫瘤
① 有遠處轉移
② 上腸繫膜動脈(SMA)被侵犯>180°，或celiac trunk被侵犯
③ 上腸繫膜靜脈(SMV)或肝門靜脈(PV)不可切除(無法重建血管) ④ 主動脈或下腔靜脈被侵犯
胰臟體部腫瘤
① 有遠處轉移
② 上腸繫膜動脈(SMA)被侵犯>180°
③ 上腸繫膜靜脈(SMV)或肝門靜脈(PV)不可切除(無法重建血管) ④ 主動脈被侵犯
胰臟尾部腫瘤
① 有遠處轉移 ② 上腸繫膜動脈(SMA)被侵犯>180° ③ 淋巴結轉移至切除範圍外

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化學治療處方建議表:輔助化療

Adjuvant chemotherapy（R0切除）（ECOG grade ≦2）	Schedule	Reference (No)/ strength of Evidence
TS-1 80-120mg/day (po 4 weeks on, 2 weeks off/ or po 2 weeks on, 1 weeks off) BSA ≧1.5m^2: 120mg /day, 1.25m^2–1.5m^2: 100mg/day, <1.25m^2 : 80mg/day	Q42 d /cycle x 4	NO.04/Level IB
Gemcitabine 1000 mg/m^2, IV,D1,D8,D15	Q28 d /cycle x 6	NO.05/Level IB NO.06 /Level IB
5-FU/LV Leucovorin 20mg/m^2, IV bolus, and then 5-FU 425mg/m^2, IV bolus, total 5 days	Q28 d/cycle x 6	NO.07/Level IB

健保用藥9.4.1：Gemcitabine限用於晚期或無法手術切除之非小細胞肺癌及胰臟癌病患。
健保用藥9.46：TS-1治療局部晚期無法手術切除或轉移性胰臟癌病人。

a. 若淋巴結陽性，符合「晚期」。可以開立健保給付之Gemcitabine與TS-1。
b. 若淋巴結陰性，不符合「晚期」。Gemcitabine與TS-1需用自費開立；或使用5-FU/LV則無給付之疑慮，但證據強度較Gemcitabine低。

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化學治療處方建議表:輔助化療

Adjuvant chemotherapy（R0切除）（ECOG grade ≦2）	Schedule	Reference (No)/ strength of Evidence
mFOLFIRINOX **Oxaliplatin** 85 mg/m^2 ,IV,2hrs **Leukovorin** 400 mg/m^2 ,IV,2hrs **Irinotecan** 150 mg/m^2 ,IV,90mins **5-FU** 2400 mg/m^2 ,IV,46hrs	Q2W /cycle x 12	NO.26/Level I

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化學治療處方建議表：新輔助化療

Chemotherapy for Neo-adjuvant (ECOG grade ≦2)	Schedule	Reference (No)/ strength of Evidence
FOLFIRINOX **Oxaliplatin** 85 mg/m^2 ,IV,2hrs **Leukovorin** 400 mg/m^2 ,IV,2hrs **Irinotecan** 180 mg/m^2 ,IV,90mins **5-FU** 400 mg/m^2 ,IV bolus **5-FU** 2400 mg/m^2 ,IV,46hrs	Q2W	NO.08/Level V
Cisplatin 50 mg/m^2, IV,D1, D15 **Gemcitabine** 1000 mg/m^2, IV,D1,D15	Q28 d	NO.17/Level V、 NO.22/Level V
mFOLFIRINOX **Oxaliplatin** 85 mg/m^2 ,IV,2hrs **Leukovorin** 400 mg/m^2 ,IV,2hrs **Irinotecan** 150 mg/m^2 ,IV,90mins **5-FU** 2400 mg/m^2 ,IV,46hrs	Q2W	NO.01/Level I

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化學治療處方建議表:局部晚期、轉移癌化療-1

Chemotherapy for unresectable、metastasis（ECOG grade ≦2）	Schedule	Reference (No)/ strength of Evidence
FOLFIRINOX **Oxaliplatin** 85 mg/m^2 ,IV,2hrs **Leukovorin** 400 mg/m^2 ,IV,2hrs **Irinotecan** 180 mg/m^2 ,IV,90mins **5-FU** 400 mg/m^2 ,IV bolus **5-FU** 2400 mg/m^2 ,IV,46hrs	Q2W	NO.08/Level IB
Gemcitabine 1000 mg/m^2, IV,D1,D8,D15	Q28 d	NO.09/Level IA
Gemcitabine 1000 mg/m^2, IV,D1,D8 **TS-1** 60-100mg/day BSA ≧1.5m^2: 100mg /day, 1.25m^2– 1.5m^2: 80mg/day, <1.25m^2 : 60mg/day,PO,D1-14	Q21 d	NO.10 /Level IB NO.15 /Level III
TS-1 80-120mg/day (po 4 weeks on, 2 weeks off/ or po 2 weeks on, 1 weeks off) BSA ≧1.5m^2: 120mg /day, 1.25m^2– 1.5m^2: 100mg/day, <1.25m^2 : 80mg/day	Q42 d /cycle	NO.10 /Level IB

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化學治療處方建議表:局部晚期、轉移癌化療-2

Chemotherapy for unresectable、metastasis（ECOG grade ≦2）	Schedule	Reference (No)/ strength of Evidence
SLOG **Gemcitabine** 800 mg/m^2 , IV, D1 **Oxaliplatin** 85 mg/m^2 ,IV,2hrs, D1 **TS-1** 35mg/m2/daily, BIDPC (Max daily dose 120mg), D1-D7 **Calcium Folinate** Folic acid(15mg/tab) 20mg/m2/daily, BID, D1-D7	Q2W/cycle	NO.20 /Level V
FIRINOX **Oxaliplatin** 85 mg/m^2 ,IV,2hrs **Irinotecan** 150 mg/m^2 ,IV,90mins **5-FU** 2400 mg/m^2 ,IV,46hrs	Q2W/ cycle x 4	NO.24/Level V
nab-paclitaxel (Abraxane)* 125 mg/m^2 , IV, D1, D8, D15 **Gemcitabine** 1000 mg/m^2 , IV, D1, D8, D15	Q4W/cycle	NO.21 /Level I

*健保用藥9.5.2：Albumin-based paclitaxel（如Abraxane):(108/11/01)限併用gemcitabine，作為轉移性胰腺癌患者之第一線治療。

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化學治療二線處方建議表-1

Chemotherapy for unresectable/recurrent disease（ECOG grade ≦2）	Schedule	Reference (No)/ strength of Evidence
Liposomal irinotecan and fluorouracil **Onivyde** *60-80 mg/m^2 ,IV, keep 90mins **Leucovorin** 400 mg/m^2 ,IV, over 30mins **5-FU** 2400 mg/m^2, IV, for 46hrs	Q2W/cycle Until progression	NO.16/Level IB
FOLFIRI **Irinotecan** 180 mg/m^2 ,IV, D1 **Leucovorin** 400 mg/m^2 ,IV, 2hrs **5-FU** 400 mg/m^2, IV bolus **5-FU** 2400 mg/m^2 ,IV,46hrs	Q2W/cycle Until progression	NO.23/Level I

*健保用藥9.12.2：Irinotecan微脂體注射劑(如Onivyde):(107/8/1)
1.與5-FU及leucovorin合併使用於曾接受過gemcitabine治療後復發或惡化之轉移性胰腺癌。
2.需經事前審查核准後使用。

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化學治療二線處方建議表-2

Chemotherapy for unresectable/recurrent disease（ECOG grade ≦2）	Schedule	Reference (No)/ strength of Evidence
FIRINOX **Oxaliplatin** 85 mg/m^2 ,IV,2hrs **Irinotecan** 150 mg/m^2 ,IV,90mins	Q2W/cycle Until progression	NO.25/Level V
SOXIRI **Oxaliplatin** 85 mg/m^2 ,IV,2hrs **Irinotecan** 150 mg/m^2 ,IV,90mins **TS-1** 80mg/m^2, BID	Q2W/cycle Until progression	NO.25/Level V

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動脈內化學放射治療處方建議表

Indications:
1.Post-operative liver metastasis from pancreatic cancer

1. Intra-arterial Chemoradiotherapy for post-operative liver metastasis(術後肝轉移，ECOG grade ≦2)	**Schedule**	**Reference (No)/ strength of Evidence**
IA Chemotherapy 5-FU D1~D5 **and IA Gemcitabine,** D1~D5 Gemcitabine 400mg/m^2/d, IA, over 30mins 5-FU 250mg/m^2/d, IA, over 24hrs from day1 to 5	Q 2~ 4 W	NO.13/Level IIB NO.18/Level IV

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放射治療處方建議表

Indication：　**Reference (No)/ strength of Evidence** N0.14/Level

(1)Adjuvant CCRT for R1 resection and R2 resection
(2)For medically fit patients but unresectable cancer without distant metastasis
(3)For medically unfit patients without distant metastasis
(4)Following CCRT, additional maintenance chemotherapy is suggested

CCRT:

(1)Radiation therapy:

Target volume: tumor bed, adjacent LN and surgical anastomosis (for post OP adjuvant CCRT)
Dose: 45-54 Gy (1.8-2 Gy/day)

(2)Chemotherapy regimen:

Gemcitabine (600 mg/m2) beginning the first day of RT (before RT), then weekly thereafter during RT

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癌症藥物停藥準則

影像學檢查，腫瘤有變大或轉移變多，應停止或改變治療方式。

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AJCC 8th 胰臟癌分期

Reference (No): 1

Table 1. Definitions for T, N, M
American Joint Committee on Cancer (AJCC) TNM Staging of Pancreatic Cancer (8th ed., 2017)

T	Primary Tumor
TX	Primary tumor cannot be assessed
T0	No evidence of primary tumor
Tis	Carcinoma *in situ* This includes high-grade pancreatic intraepithelial neoplasia (PanIn-3), intraductal papillary mucinous neoplasm with high-grade dysplasia, intraductal tubulopapillary neoplasm with high-grade dysplasia, and mucinous cystic neoplasm with high-grade dysplasia
T1	Tumor ≤2 cm in greatest dimension
T1a	Tumor ≤0.5 cm in greatest dimension
T1b	Tumor >0.5 cm and <1 cm in greatest dimension
T1c	Tumor 1–2 cm in greatest dimension
T2	Tumor >2 cm and ≤4 cm in greatest dimension
T3	Tumor >4 cm in greatest dimension
T4	Tumor involves the celiac axis, superior mesenteric artery, and/or common hepatic artery, regardless of size

N	Regional Lymph Nodes
NX	Regional lymph nodes cannot be assessed
N0	No regional lymph node metastases
N1	Metastasis in one to three regional lymph nodes
N2	Metastasis in four or more regional lymph nodes

M	Distant Metastasis
M0	No distant metastasis
M1	Distant metastasis

Table 2. AJCC Prognostic Groups

	T	N	M
Stage 0	Tis	N0	M0
Stage IA	T1	N0	M0
Stage IB	T2	N0	M0
Stage IIA	T3	N0	M0
Stage IIB	T1, T2, T3	N1	M0
Stage III	T1, T2, T3	N2	M0
	T4	Any N	M0
Stage IV	Any T	Any N	M1

Reference-1

1.NCCN guideline Version 1.2021 – Pancreatic Adenocarcinoma

2.NHRI/TCOG Cancer Practice Guideline – Pancreatic Cancer

3.Seufferlein T, Bachet JB, Van Cutsem E, Rougier P; ESMO Guidelines Working Group: Pancreatic adenocarcinoma: ESMO-ESDO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2012 Oct;23 Suppl 7:vii33-40.

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10. Hideki Ueno et al. Randomized Phase III Study of Gemcitabine Plus S-1, S-1 Alone, or Gemcitabine Alone in Patients With Locally Advanced and Metastatic Pancreatic Cancer in Japan and Taiwan: GEST Study(J Clin Oncol 31:1640-1648).

11.Liu F, Tang Y, Sun J, Yuan Z, Li S, Sheng J, Ren H, Hao J. Regional Intra-Arterial vs. systemic Chemotherapy for Advanced Pancreatic Cancer: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. PLoS ONE 2012;7(7):e40847.

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Reference-2

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