高 雄 榮 民 總 醫 院
胰臟癌診療原則

2019年02月26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：2018/02/27(第一版)

2018/10/16(第二版)

本共識與上一版的差異

上一版	新版
1. 原unresectable、metastasis化療處方: FOLFIRINOX、Gemcitabine、Gemcitabine+ TS-1、TS-1。 2. 二線藥物:Onivyde為自費藥物。	1. 新增unresectable、metastasis化療處方: SLOG (P.10) 2. 二線藥物: Onivyde於2018年8月通過健保給付，新增給付條件說明。(P.11)

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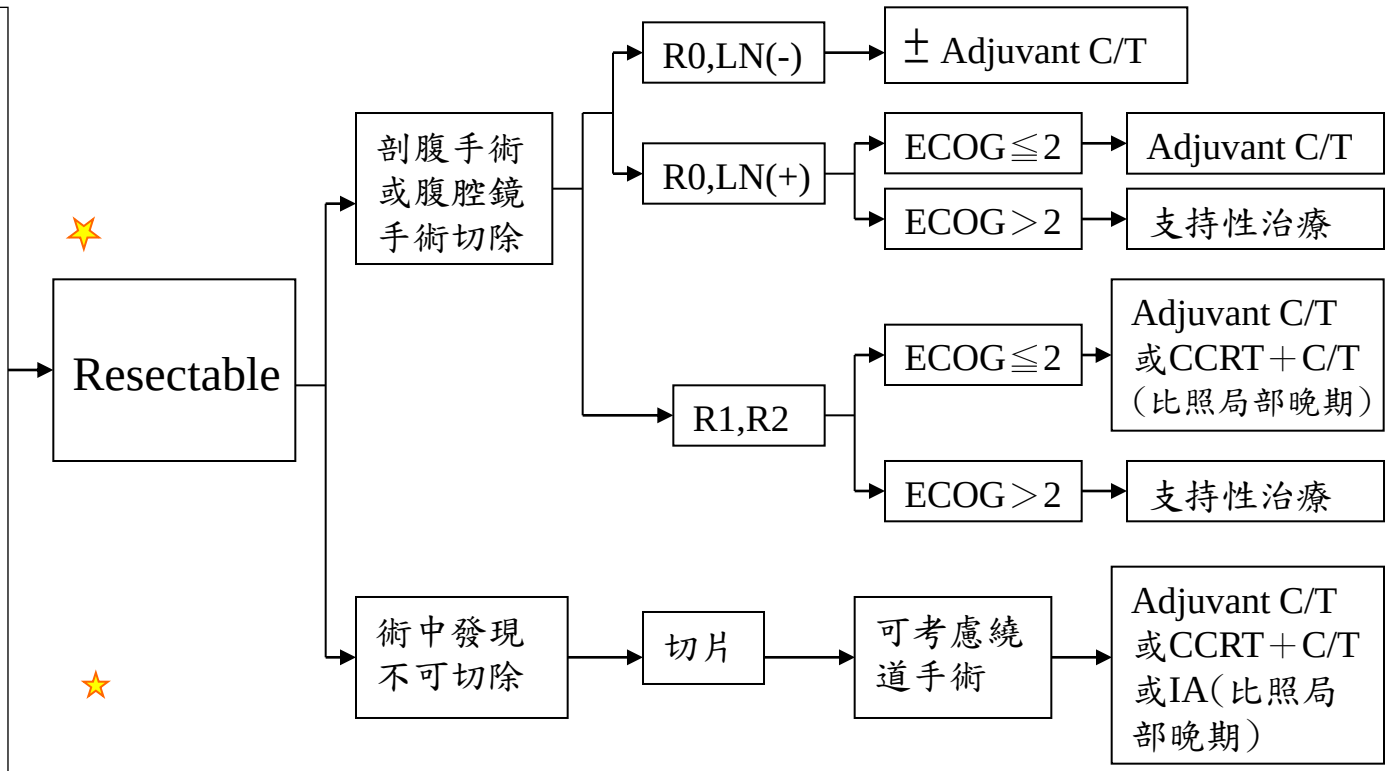
臨床診療指引　2019年第一版

評估	診斷	治療	追蹤

- 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)
- 腹部超音波#
- 腹部電腦斷層攝影 (CT)*
- 核磁共振檢查(MRI)*
- 正子攝影檢查(PET)*
- 內視鏡超音波＋FNA
- 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



※ 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

膽道阻塞 Resectable	Unresectable
術前膽管炎 → 塑膠支架或體外引流 (PTCD or PTGBD)	術前膽管炎、黃疸 → 塑膠支架 / 金屬支架 / 體外引流(PTCD or PTGBD)
術前黃疸但無膽管炎 → 不需引流	

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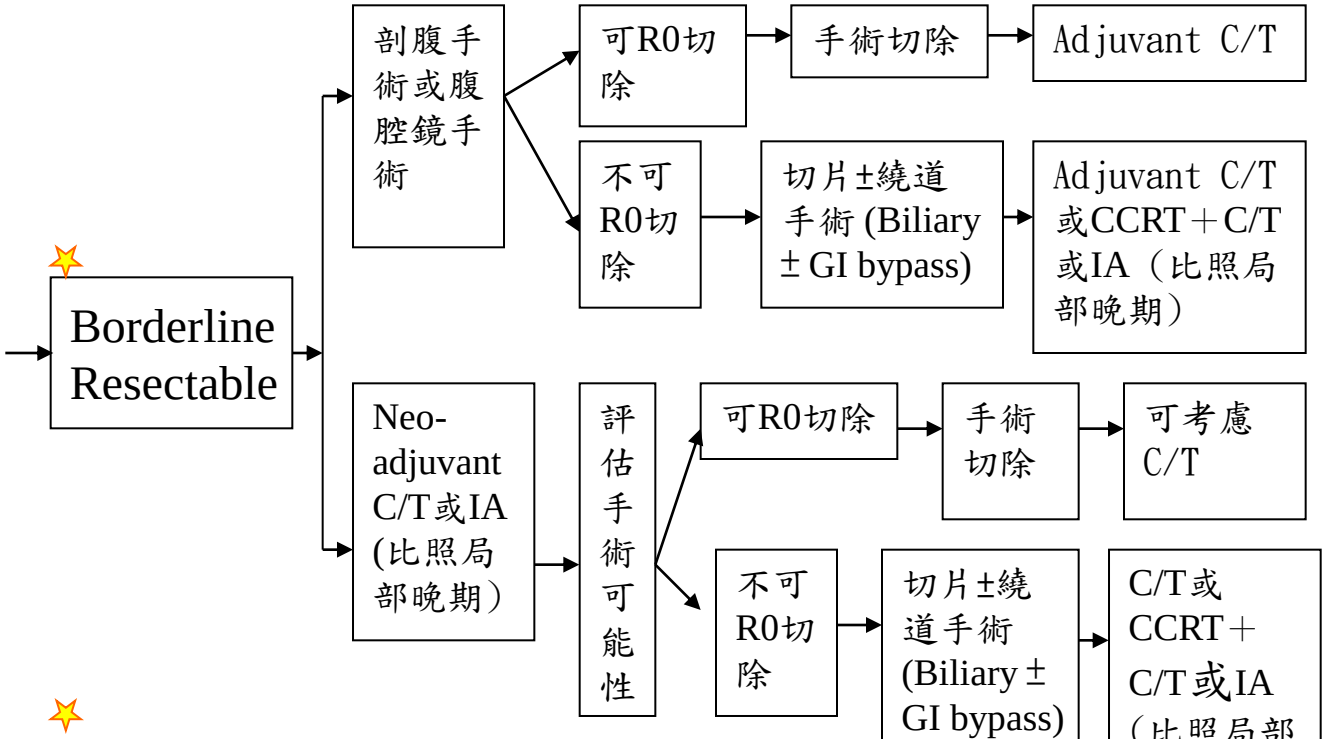

如有黃疸症狀

- 金屬支架
- 塑膠支架
- 體外引流(PTCD or PTGBD)

※
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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*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

Unresectable
Locally advanced

遠處轉移

日常體能狀態(ECOG)

Grade 0-2

CT-GUIDED/EXPLORATORY LAPA切片或EUS+FNA 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

Grade ＞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(PTCD or PTGBD)

※ 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

＊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：新輔助化療

Chemotherapy for neoadjuvant　（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

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化學治療處方建議表: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: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

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化學治療二線處方建議表

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

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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動脈內化學放射治療處方建議表

Indications:
1.Unresectable, only liver metastases, with or without regional lymph nodes
2.Post-operative liver metastasis from pancreatic cancer

Intra-arterial Chemoradiotherapy for unresectable, only liver metastases or post-operative liver metastasis (局部晚期僅肝轉移或術後肝轉移，ECOG grade ≦2)	**Schedule**	**Reference (No)/ strength of Evidence**
IA Chemotherapy 5-FU D1~D5 **and IV Gemcitabine,** D1 5-FU 750-1000mg/m^2/d, IA, 5hrs Gemcitabine 1000mg/m^2/d, IV, 30mins	Q4W	NO.13/Level IIB NO.18/Level IV NO.19/Level III

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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。

Reference

1.NCCN guideline Version 2.2015 – 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.

4. Akira Fukutomi et al. JASPAC 01 trial (ASCO 2013)

5. Helmut Oettle et al. Adjuvant Chemotherapy With Gemcitabine vs Observation in Patients Undergoing Curative-Intent Resection of Pancreatic Cancer. (JAMA. 2007; 297:267-277).

6. H Ueno et al. A randomised phase III trial comparing gemcitabine with surgery-only in patients with resected pancreatic cancer: Japanese Study Group of Adjuvant Therapy for Pancreatic Cancer.(British Journal of Cancer 2009, 101, 908 – 915) .

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8. Thierry Conroy et al. FOLFIRINOX versus Gemcitabine for Metastatic Pancreatic Cancer. (N Engl J Med 2011;364:1817-25).

9. H A Burris 3rd et al. Improvements in survival and clinical benefit with gemcitabine as first-line therapy for patients with advanced pancreas cancer: a randomized trial. (J Clin Oncol. 1997 Jun;15(6):2403-13)

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).

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17. Volker Heinemann et al. Randomized Phase III Trial of Gemcitabine Plus Cisplatin Compared With Gemcitabine Alone in Advanced Pancreatic Cancer. J Clin Oncol 24:3946-3952; 2006.

18. Hidehiro Tajima et al. Hepatic arterial infusion chemotherapy with gemcitabine and 5-fluorouracil or oral S-1 improves the prognosis of patients with postoperative liver metastases from pancreatic cancer. MOLECULAR AND CLINICAL ONCOLOGY 1: 869-874, 2013.

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