

高雄榮民總醫院

胰臟癌臨床診療指引

2015年第二版

癌症中心胰臟癌醫療團隊擬定

2015年第二版為參考國家衛生研究院出版之胰臟癌臨床指引及其他參考文獻，於2015.09.15由胰臟癌團隊相關人員陳以書、康朥翔、蔡忠育、江佳陵、陳海雄、張國楨、李懷寶、葉昶宏等人討論後共同修訂。

注意事項：這個診療準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，直接引用這個研究資訊及診療準則並不恰當。
只有你的醫師才能決定給你最恰當的治療。

會議討論日期

- 上次會議：20150107, 20150915
- 本共識與上一版的差異
 - 增加癌症藥物停藥準則

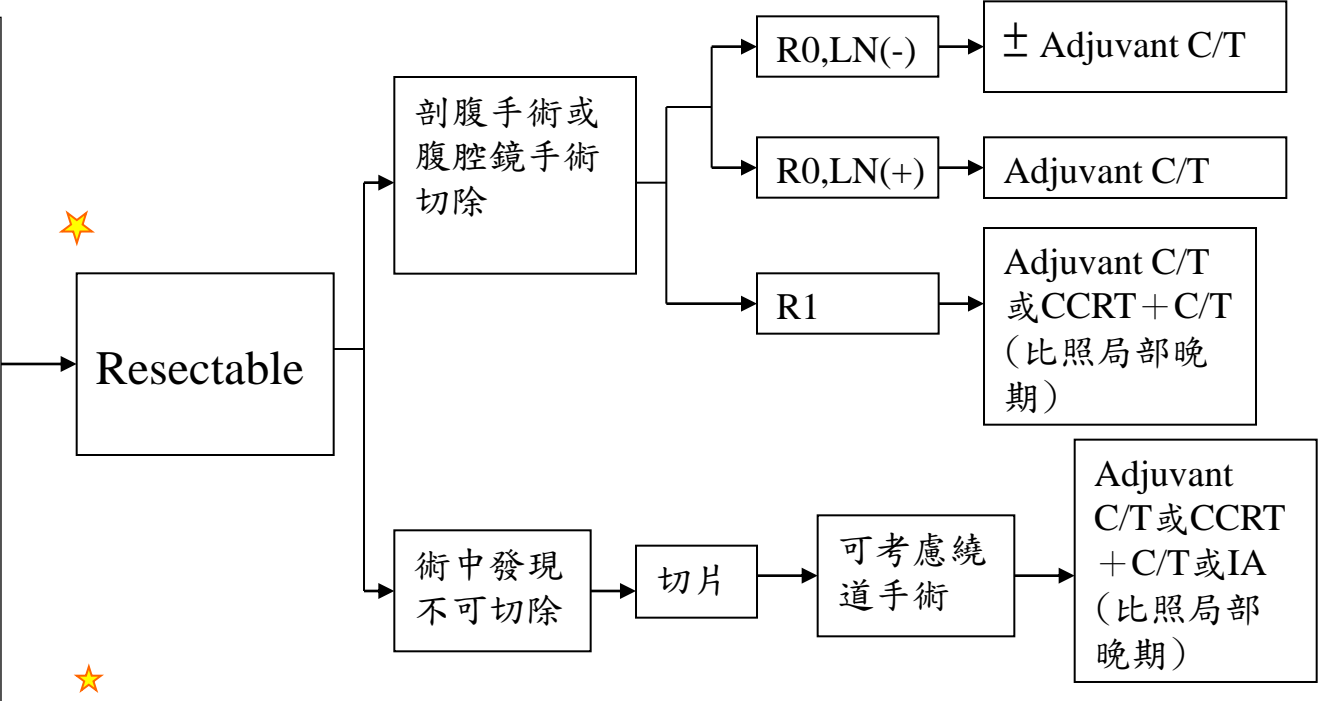
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評估	診斷	治療	追蹤
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- 病史，理學檢查
 - 營養及日常體能狀態
 - 胸部X光
 - 血液常規
 - 電解質及肝腎功能
 - 腫瘤指標 (CEA, Ca19-9)
 - 腹部超音波
 - 腹部電腦斷層攝影
 - 核磁共振檢查
 - 內視鏡超音波 + FNA
 - 經內視鏡逆行性膽胰管攝影術 (ERCP)
- 必要時評估 →
- 腹腔鏡



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

膽道阻塞 Resectable	Unresectable
術前膽管炎 → 暫時性支架 體外引流 術前黃疸但無膽管炎 → 不需引流	術前膽管炎 → 繞道手術 (Biliary ± GI bypass) 永久性支架流 體外引流

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Borderline Resectable

剖腹手術或腹腔鏡手術

可R0切除

手術切除

Adjuvant C/T

不可R0切除

切片 ± 繞道手術 (Biliary ± GI bypass)

Adjuvant C/T 或 CCRT + C/T 或 IA (比照局部晚期)

Neo-adjuvant C/T 或 IA (比照局部晚期)

評估手術可能性

可R0切除

手術切除

可考慮 C/T

不可R0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)

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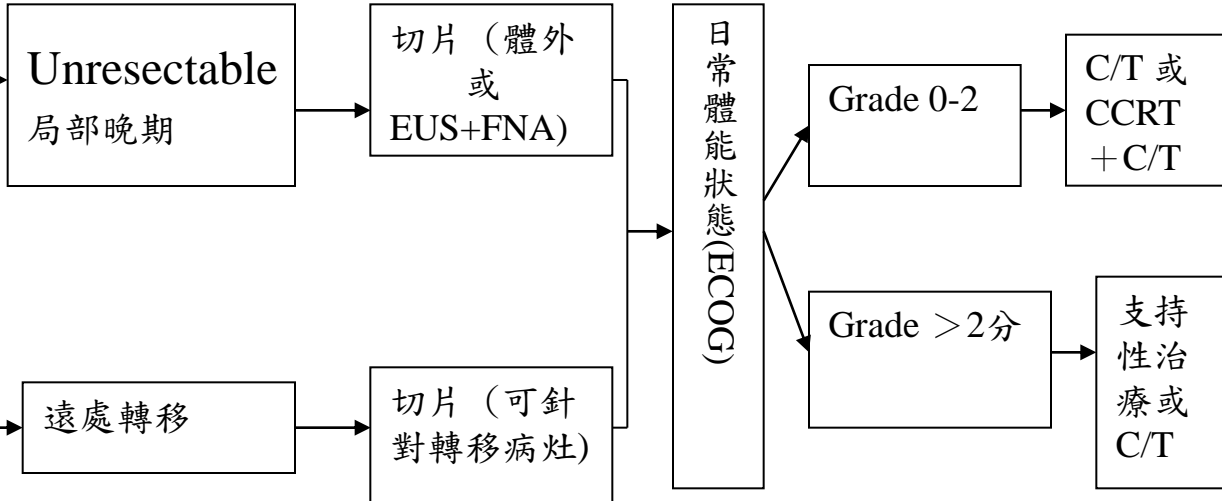
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 Every 3 months for 2 years
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 ※ CXR
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 ※ Abdominal CT or MRI
 Annually for 3 years then as clinically indicated

* 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 $>180^\circ$ ，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 $>180^\circ$
- 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 $>180^\circ$
- 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

Adjuvant chemotherapy (R0切除)	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 $\geq 1.5\text{m}^2$: 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。

- 若淋巴結陽性，符合「晚期」。可以開立健保給付之Gemcitabine與TS-1。
- 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

Chemotherapy for unresectable (ECOG grade 0-2)	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
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

Chemotherapy for unresectable (ECOG grade > 2)	Schedule	Reference (No)/ strength of Evidence
Gemcitabine 1000 mg/m ² , IV,D1,D8,D15	Q28 d	NO.09/Level IA
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
支持性治療		

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動脈內化學放射治療處方建議表

Indications:

- 1.Borderline resectable , 術中發現不可切除
- 2.Unresectable, locally advanced, with or without regional lymph nodes
- 3.Unresectable, liver only metastases, with or without regional lymph nodes

Intra-arterial Chemoradiotherapy for unresectable (局部晚期或肝轉移 , ECOG grade 0-2)	Schedule	Reference (No)/ strength of Evidence
IA Chemotherapy regimen (IA port implantation) Gemcitabine 100 mg/m ² /d; 5-FU 200 mg/m ² /d; cisplatin 10 mg/m ² /d; MMC 2 mg/m ² /d, leucovorin 15mg/m ² /d, d1-5 Radiation therapy 2 Gy/d for 5 days, 4wks, total 40-50 Gy	d1-d5, IA CCRT d8-d12, R/T d15-d19, R/T d21-d25, R/T Followed by IA C/T on d1-d5/28-d cycle until disease progression	NO.11/Level IA, NO.12/Level IB NO.13/Level IIB

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 1.2015 – 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) .
7. John P. Neoptolemos et al. Adjuvant Chemotherapy With Fluorouracil Plus Folinic Acid vs Gemcitabine Following Pancreatic Cancer Resection (*JAMA.* 2010: 1073-1081).
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).
- 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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12. Tanaka T, Sakaguchi H, Anai H, Yamamoto K, Morimoto K, Tamamoto T, Kichikawa K. Arterial Infusion of 5-Fluorouracil Combined with Concurrent Radiotherapy for Unresectable Pancreatic Cancer: Results from a Pilot Study. *AJR* 2007; 189:421–428.
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14. Gemcitabine Alone Versus Gemcitabine Plus Radiotherapy in Patients With Locally Advanced Pancreatic Cancer: AN Eastern Cooperative Oncology Group Trial. *J Clin Oncol* 2011 Nov 1;29(31):4105-12.