

# 高雄榮民總醫院

## 胰臟癌診療原則

2018年10月16日 第二版

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

## 本共識與上一版的差異

上一版	新版
<ol style="list-style-type: none"><li>1. 針對resectable病患術後治療無ECOG分及選擇。</li><li>2. 動脈化療處方適應症為「局部晚期或肝轉移」，化療處方:IA Chemotherapy(5-FU+ Gemcitabine ) and IV Gemcitabine, D1, D8, D15。</li></ol>	<ol style="list-style-type: none"><li>1. 新增Adjuvant化療依照ECOG分級選擇。(P.3、P.7)</li><li>2. 依據文獻更改動脈化療處方適應症為「局部晚期僅肝轉移或術後肝轉移」及化療處方:IA Chemotherapy 5-FU D1~D5 and IV Gemcitabine, D1。(P.11)</li></ol>

# 胰臟腺癌

高雄榮民總醫院  
臨床診療指引

2018年 第二版

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<sup>#</sup>
- 血液常規
- 電解質及肝腎功能
- 腫瘤指標 (CEA, Ca19-9)
- 腹部超音波<sup>#</sup>
- 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)

<sup>#</sup>與癌症期別相關之次要檢查

Resectable

剖腹手術  
或腹腔鏡  
手術切除

術中發現  
不可切除

R0, LN(-)

R0, LN(+)

R1, R2

切片

治療

± Adjuvant C/T

ECOG ≤ 2

ECOG > 2

ECOG ≤ 2

ECOG > 2

可考慮繞  
道手術

Adjuvant C/T

支持性治療

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

支持性治療

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

追蹤

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

膽道阻塞 Resectable

術前膽管炎

塑膠支架或體外引流

(PTCD or PTGBD)

術前黃疸但無膽管炎

不需引流

Unresectable

術前膽管炎、黃疸

塑膠支架

金屬支架

體外引流 (PTCD or PTGBD)

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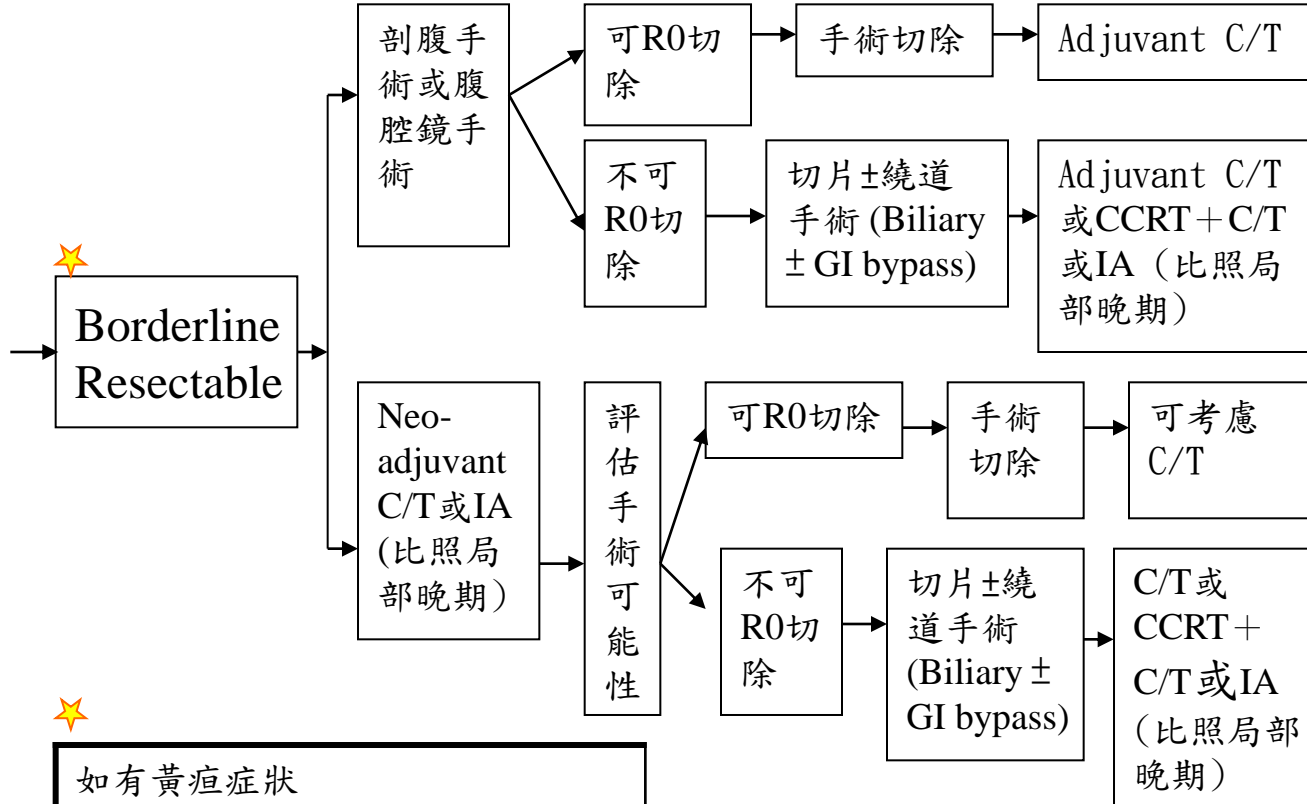
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評估	診斷	治療	追蹤
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- 病史，理學檢查
- 營養及日常體能狀態
- 胸部X光<sup>#</sup>
- 血液常規
- 電解質及肝腎功能
- 腫瘤指標 (CEA, Ca19-9)
- 腹部超音波<sup>#</sup>
- 腹部電腦斷層攝影 (CT)\*
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- 內視鏡超音波 + FNA
- 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)

<sup>#</sup>與癌症期別相關之次要檢查



- ★ 如有黃疸症狀
- 金屬支架
  - 塑膠支架
  - 體外引流 (PTCD or PTGBD)

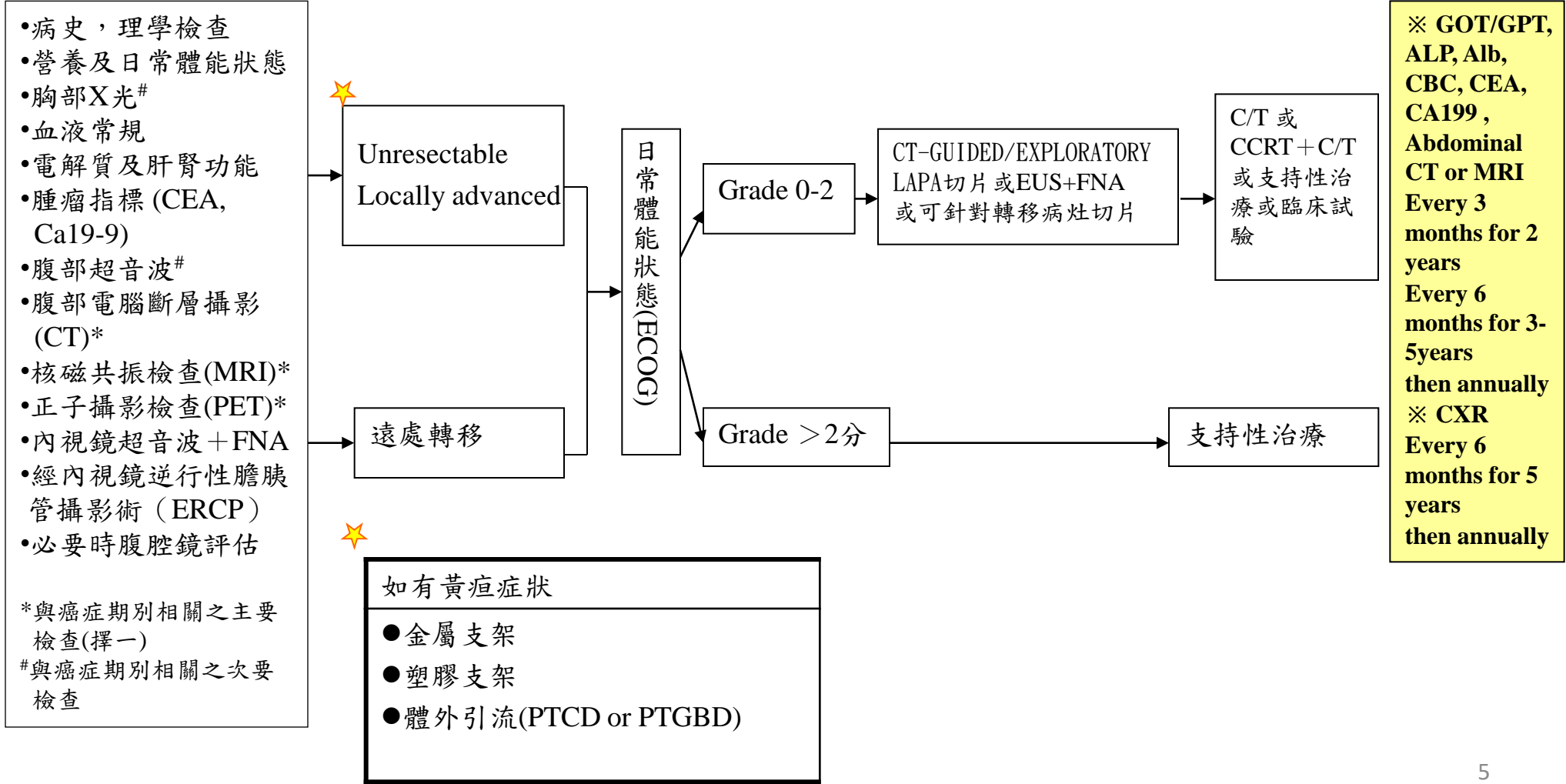
※ GOT/GPT, ALP, Alb, CBC, CEA, CA199, Every 6 months Abdominal CT or MRI Every 3 months for 2 years for 3-5 years then annually  
 ※ CXR Every 6 months for 5 years then annually

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評估	診斷	治療	追蹤
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\* 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 $180^\circ$

\* 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

# 胰臟腺癌

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## 化學治療處方建議表：輔助化療

Adjuvant chemotherapy (R0切除) (ECOG grade $\leq 2$ )	Schedule	Reference (No)/ strength of Evidence
<b>TS-1</b> 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, $1.25\text{m}^2$ - $1.5\text{m}^2$ : 100mg/day, < $1.25\text{m}^2$ : 80mg/day	Q42 d /cycle x 4	NO.04/Level IB
<b>Gemcitabine</b> 1000 mg/m <sup>2</sup> , IV,D1,D8,D15	Q28 d /cycle x 6	NO.05/Level IB NO.06 /Level IB
<b>5-FU/LV</b> Leucovorin 20mg/m <sup>2</sup> , IV bolus, and then 5-FU 425mg/m <sup>2</sup> , 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：新輔助化療

Chemotherapy for neoadjuvant (ECOG grade $\leq 2$ )	Schedule	Reference (No)/ strength of Evidence
<b>FOLFIRINOX</b> <b>Oxaliplatin</b> 85 mg/m <sup>2</sup> ,IV,2hrs <b>Leukovorin</b> 400 mg/m <sup>2</sup> ,IV,2hrs <b>Irinotecan</b> 180 mg/m <sup>2</sup> ,IV,90mins <b>5-FU</b> 400 mg/m <sup>2</sup> ,IV bolus <b>5-FU</b> 2400 mg/m <sup>2</sup> ,IV,46hrs	Q2W	NO.08/Level V
<b>Cisplatin</b> 50 mg/m <sup>2</sup> , IV,D1, D15 <b>Gemcitabine</b> 1000 mg/m <sup>2</sup> , 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

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

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## 化學治療二線處方建議表

Chemotherapy for unresectable/recurrent disease ( ECOG grade $\leq 2$ )	Schedule	Reference (No)/ strength of Evidence
<b>Liposomal irinotecan and fluorouracil</b> <b>Onivyde</b> 60-80 mg/m <sup>2</sup> ,IV, keep 90mins <b>Leucovorin</b> 400 mg/m <sup>2</sup> ,IV, over 30mins <b>5-FU</b> 2400 mg/m <sup>2</sup> , IV, for 46hrs	Q2W/cycle Until progression	NO.16/Level IB

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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

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

## 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/m<sup>2</sup> ) 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) .
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 3<sup>rd</sup> 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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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.
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16. Andrea Wang-Gillam et al. Nanoliposomal irinotecan with fluorouracil and folinic acid in metastatic pancreatic cancer after previous gemcitabine-based therapy (NAPOLI-1): a global, randomised, open-label, phase 3 trial. *Lancet* 2016; 387: 545–57.
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