前言

肝癌是國人常見的惡性腫瘤，和病毒性肝炎的關聯性更是社會基本常識。有關肝癌的早期診斷及慢性病毒性肝炎帶原者的篩檢，是相關醫療團隊的重要課題。和其他癌症不同的是原發性肝細胞癌在歐美先進國家的盛行率和國內相差很大，因此為制定符合國情之肝癌診療規範，自民國94年招集相關次專科制定本院肝癌診療指引。本年度延續多專科團隊會議機制，參酌NCCN指引及國內外相關文獻，進行指引改版，以期更貼近國內民情及國際肝癌診療潮流。

本共識依下列參考資料修改版本：

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Laparoscopic liver resection for peripheral hepatocellular carcinoma in patients with chronic liver disease: midterm results and perspectives. Cherqui D, Laurent A, Tayar C, Chang S, Van Nhieu JT, Loriau J, Karoui M, Duvoux C, Dhumeaux D, Fagniez PL.Ann Surg. 2006 Apr;243(4):499-506. A phase II trial of thalidomide plus tegafur/uracil for patients with advanced/metastatic hepatocellular carcinoma (HCC): Final report. C. Hsu, Z. Lin, K. Lee, K. Yeh, C. Hsiao, Y. Shen, D. Chang, S. Wang, C. Hsu and A. Cheng. J Clin Oncol. 2009; 27 (15S).

Thalidomide plus tegafur/uracil for the treatment of advanced/metastatic hepatocellular carcinoma (HCC): A phase II single-arm study. C. Hsu, D. Chang, Z. Lin, K. Lee, C. Hsiao, Y. Shen, A. Cheng and C. Hsu. J Clin Oncol. 2008; 26(15S).

Efficacy and safety of thalidomide in patients with hepatocellular carcinoma. Hsueh-Erh Chiou, Tsang-En Wang, Ying-Yue Wang, Hui-Wen Liu. 2006 Nov 21; 12(43): 6955-6960.

Effect of Thalidomide in Hepatocellular Carcinoma: Assessment with Power Doppler US and Analysis of Circulating Angiogenic Factors[1]. Hsu et al. Radiology 2005 May; 235:509–516.

Hepatocellular Carcinoma with Intra-Atrial Tumor Thrombi A Report of Three Cases Responsive to Thalidomide Treatment and Literature Review. Jang-Yang Changa, Wann-Shen Kab, Tsu-Yi Chaoc, Tsang-Wu Liua, Tsai-Rong Chuanga, Li-Tzong Chena. Oncology 2004;67:320-326.

Salvage therapy for hepatocellular carcinoma with thalidomide. Tsang-En Wang, Chin-Roa Kao, Shee-Chan Lin, Wen-Hsiung Chang, Cheng-Hsin Chu, Johson Lin, Ruey-Kuen Hsieh. World J Gastroenterol 2004;10(5):649-653

Low-Dose Thalidomide Treatment for Advanced Hepatocellular Carcinoma. Chiun Hsua, c,d Chiung-Nien Chenb Li-Tzong Chenf,g Chen-Yao Wua Pei-Ming Yangc Ming-Yang Laic,d Po-Huang Leeb Ann-Lii Chenga. Oncology 2003;65:242–249

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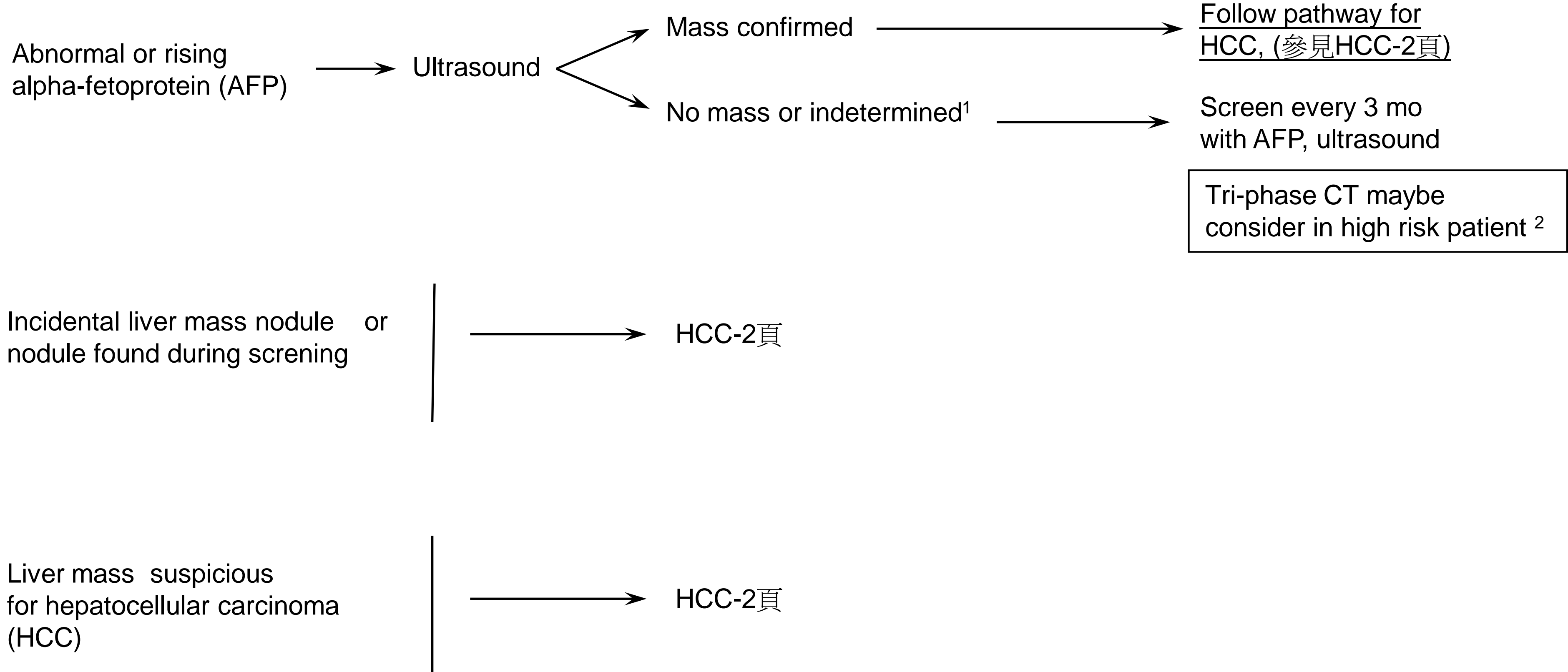
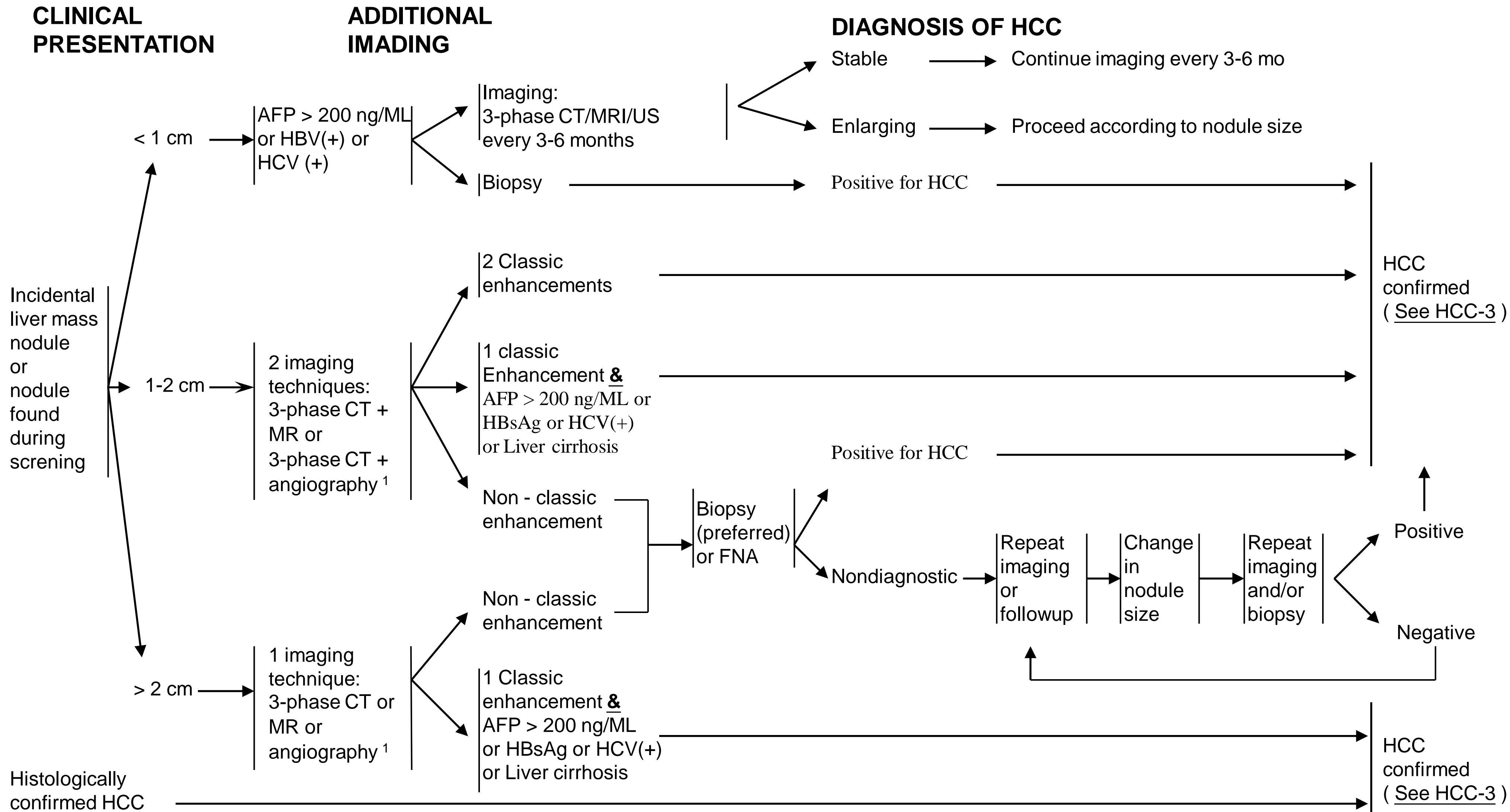
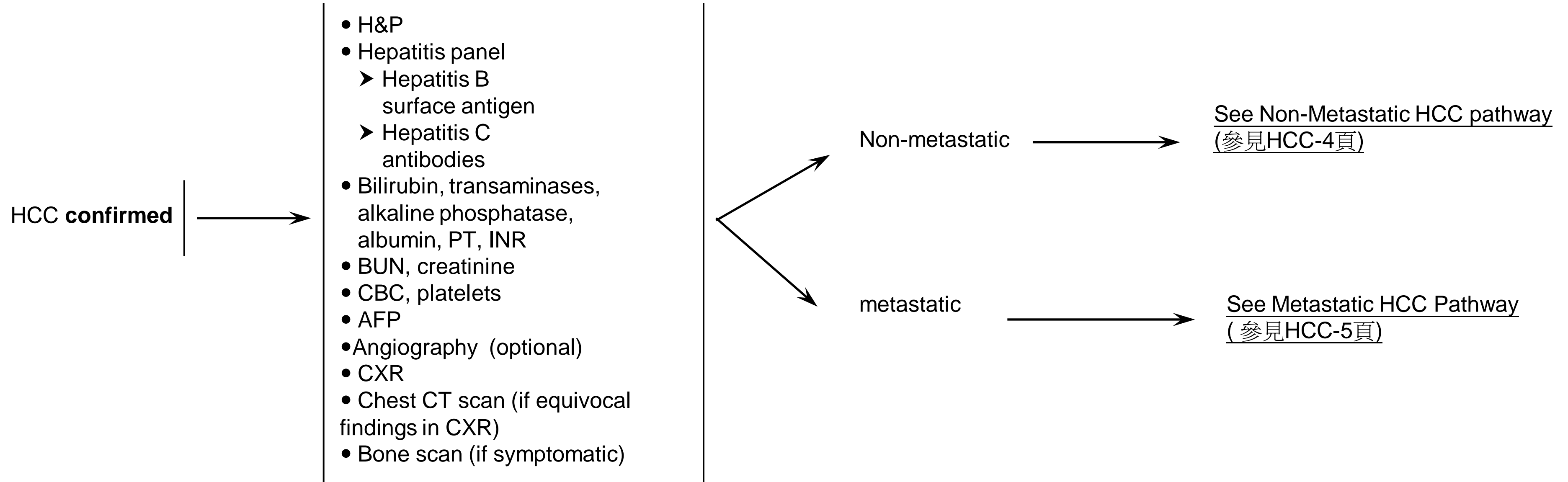


[1] Rule out germ cell tumor if clinically indicated.

[2] high risk patient：HBV carrier, HCV carrier, cirrhosis liver, progressive elevation of the AFP, Family history.



[1] 若病人一發現即爲end stage HCC，選擇 supportive / hospice care，在診斷期不強制CT or MR or angiography 。


CLINICAL PRESENTATION
WORK-UP
HCC confirmed
• H&P
• Hepatitis panel
➤ Hepatitis B surface antigen
➤ Hepatitis C antibodies
• Bilirubin, transaminases, alkaline phosphatase, albumin, PT, INR
• BUN, creatinine
• CBC, platelets
• AFP
• Angiography (optional)
• CXR
• Chest CT scan (if equivocal findings in CXR)
• Bone scan (if symptomatic)
Non-metastatic
See Non-Metastatic HCC pathway (參見HCC-4頁)
metastatic
See Metastatic HCC Pathway (參見HCC-5頁)

CLINICAL PRESENTATION

MANAGEMENT

SURVEILLANCE

Non-metastatic HCC

→ Anatomically resectable → •BLCL 0,A,B, C[1] •Consider Liver reserve[1,2] •Consider comorbidity [3]

- → Good liver reserve (Child A) with/without comorbidity / Fair liver reserve (Child B) with/without comorbidity → Resection (**prefer**) Or • Locoregional therapy ‣ Ablation ‣ TACE ‣ Externally-beam radiation therapy (conformal or stereotactic) (category 2B)
- → UCSF criteria： single tumor ≤ 6.5cm, maximum of 3 tumors with none > 4.5cm, cumulative tumor size ≤ 8cm. → Transplant [4]

→ • Imaging every 3 mo for 2 y, then every 6-12 mo [8] • AFP, every 3 mo for 2 y, then every 6-12 mo [8] → **Recurrence/ Metastasis** (參見HCC-5頁)

→ Anatomically Unresectable

- → UCSF criteria (as above) → Transplant [4]
- → •BLCL C[1] •Consider Liver reserve[1,2] •Consider comorbidity [3] → Good liver reserve (Child A) with/without comorbidity / Fair liver reserve (Child B) with/without comorbidity → **Options:**
  - • Locoregional therapy
  - ‣ Ablation (參見HCC-6頁)
  - ‣ TACE (參見HCC-6頁)
  - ‣ Externally-beam radiation therapy (conformal or stereotactic) (category 2B) (參見HCC-6頁)
  - • Systemic therapy
  - ‣Sorafenib [5]
  - ‣ Chemotherapy (if adequate liver reserve and performance status[3]) [6]
  - • Clinical trial
  - • Supportive care / hospice care

  → **Recurrence/ Metastasis** (參見HCC-5頁)
- → •BLCL D[1] → • Supportive care / hospice care

[1] BCLC classification (參見HCC-8頁); Child-Pugh Score (參見HCC-7頁)

[2] ICG test is optional, and strongly recommended if massive resection is required.

[3] consider age and ECOG performance status scale (參見HCC-8頁)

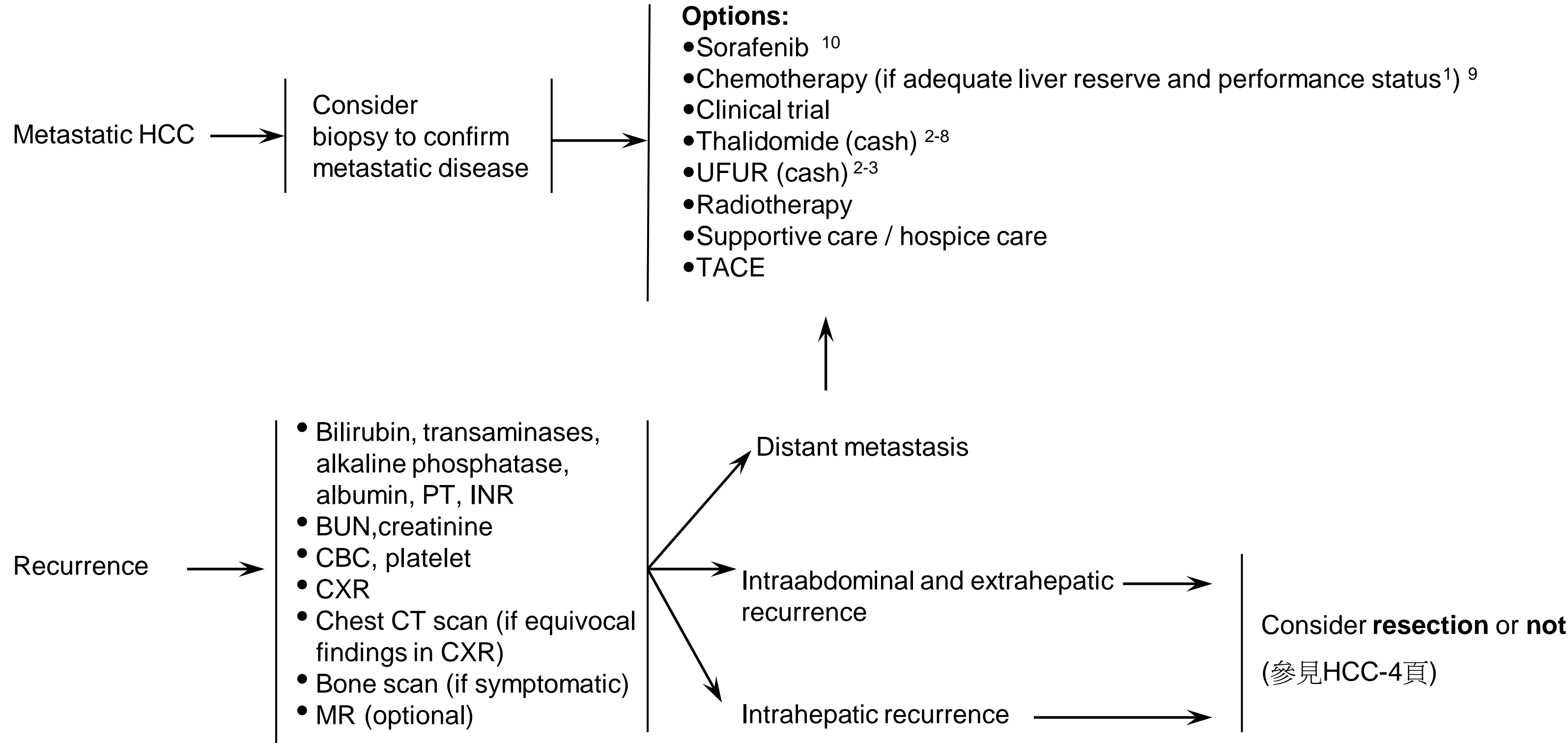
[4] IF patient conforms to transplant criteria, discuss the transplant procedure in the quite early stage with patient and family members.

[5] Sorafenib 健保條件: Ⅰ.肝外轉移（遠端轉移或肝外淋巴結侵犯）的Child-Pugh A class患者。Ⅱ.大血管侵犯（腫瘤侵犯主門靜脈或侵犯左/右靜脈第一分支）的Child-Pugh A class患者。

[6]Refer to Chemotherapy regimen as HCC-11頁

[7]Case series and single-arm studies suggest safety and possible efficacy of radiation therapy in selected cases.

[8]國民健康署 核心測量指標(肝癌)：治療後2個月內追蹤影像學（US, CT, MRI任一）, 治療前AFP>20ng/ml 的肝癌病人，治療後2個月內追蹤AFP （包括Curative、TA(C)E）



[1] ECOG performance status scale (參見HCC-8頁).
[2] A phase II trial of thalidomide plus tegafur/uracil for patients with advanced/metastatic hepatocellular carcinoma (HCC): Final report. C. Hsu, Z. Lin, K. Lee, K. Yeh, C. Hsiao, Y. Shen, D. Chang, S. Wang, C. Hsu and A. Cheng. J Clin Oncol. 2009; 27 (15S).
[3] Thalidomide plus tegafur/uracil for the treatment of advanced/metastatic hepatocellular carcinoma (HCC): A phase II single-arm study. C. Hsu, D. Chang, Z. Lin, K. Lee, C. Hsiao, Y. Shen, A. Cheng and C. Hsu. J Clin Oncol. 2008; 26(15S).
[4] Efficacy and safety of thalidomide in patients with hepatocellular carcinoma. Hsueh-Erh Chiou, Tsang-En Wang, Ying-Yue Wang, Hui-Wen Liu. 2006 Nov 21; 12(43): 6955-6960.
[5] Effect of Thalidomide in Hepatocellular Carcinoma: Assessment with Power Doppler US and Analysis of Circulating Angiogenic Factors1. Hsu et al. Radiology 2005 May; 235:509–516.
[6] Hepatocellular Carcinoma with Intra-Atrial Tumor Thrombi A Report of Three Cases Responsive to Thalidomide Treatment and Literature Review. Jang-Yang Changa, Wann-Shen Kab, Tsu-Yi Chaoc, Tsang-Wu Liua, Tsai-Rong Chuanga, Li-Tzong Chena. Oncology 2004;67:320-326.
[7] Salvage therapy for hepatocellular carcinoma with thalidomide. Tsang-En Wang, Chin-Roa Kao, Shee-Chan Lin, Wen-Hsiung Chang, Cheng-Hsin Chu, Johson Lin, Ruey-Kuen Hsieh. World J Gastroenterol 2004;10(5):649-653
[8] Low-Dose Thalidomide Treatment for Advanced Hepatocellular Carcinoma. Chiun Hsua, c,d Chiung-Nien Chenb Li-Tzong Chenf,g Chen-Yao Wua Pei-Ming Yangc Ming-Yang Laic,d Po-Huang Leeb Ann-Lii Chenga. Oncology 2003;65:242–249
[9] Refer to Chemotherapy regimen as HCC-11頁
[10] Sorafenib 健保條件: Ⅰ.肝外轉移（遠端轉移或肝外淋巴結侵犯）的Child-Pugh A class患者。Ⅱ.大血管侵犯（腫瘤侵犯主門靜脈或侵犯左/右靜脈第一分支）的Child-Pugh A class患者

1. Criteria for TACE:

(1) Adequate liver reserve

(2) Patent main portal vein

(3) No bleeding tendency

2. Criteria for percutaneous ablation (alcohol, cryotherapy, radiofrequency, or microwave):

(1) No ascites

(2) Platelet $\geq$ 50,000/mm^3, PT prolongation $\leq$ 5 seconds or $\leq$ 3 seconds after correction

(3) Ultrasound or CT identifiable and approachable lesions[1]

(4) Patients can cooperate[1]

(5) Number of liver tumors $\leq$ 3, each size $\leq$ 5 cm

3. Criteria for conformal radiotherapy:

(1) Main portal vein thrombosis(+)

(2) Adequate liver reserve

(3) Not indicated for TAE (or TACE), ablation or chemotherapy

[1] If the lesions are not identifiable or approachable or the patient can't cooperate, laparoscopic radiofrequency ablation under general anesthesia is optional.

A. Child-Pugh Score

CHILD-PUGH SCORE			
Chemical and Biochemical Parameters	Scores (points) for Increasing Abnormality		
	1	2	3
Encephalopathy	None	1-2	3-4
Ascites	None	Slight	Moderate
Albumin(g/dl)	>3.5	2.8-3.5	<2.8
Prothrombin time prolonged (sec)	1-4	4-6	>6
Bilirubin (mg/dl) [For primary biliary cirrhosis]	< 2 [< 4]	2-3 [4-10]	>3 [>10]

Class A = 5-6 points; Class B = 7-9 points; Class C = 10-15 points.

B. ECOG Performance status scale:

ECOG Scale	Description
0	Asymptomatic; normal activity
1	Symptomatic; ambulatory; Able to carry out activities of daily living
2	Symptomatic; In bed less than 50% of the day; Occasionally needs nursing care.
3	Symptomatic; In bed more than 50% of the day.
4	Bedridden; may need hospitalization.

Note: ECOG = Eastern Cooperative Oncology Group.

Barcelona-Clinic Liver Cancer (BCLC) classification

Stage	Tumor Features	Child-Pugh Score	Performance Status Test (PST)
Stage 0	Single≦2 cm Carcinoma in situ	Child-Pugh A	0
Stage A	Single ≦5cm or 3 nodulars <3 cm	Child-Pugh A-B	0
Stage B	Single ＞5cm or multinodulars	Child-Pugh A-B	0
Stage C	Portal invasion **N1, M1**	Child-Pugh A-B	1-2
Stage D	Any	Child-Pugh C	3-4

*BCLC期別摘錄規則依據 行政院衛生署國民健康局 書函 (發文字號:國健癌字第1000302045號)，2015/3/23更新

*有distant metastasis,至少就是stage C (不論primary tumor到底是幾顆or多大)

Staging[1]

American Joint Committee on Cancer (AJCC) TNM Staging for Liver Tumors. [7th Ed – 2010]

PRIMARY TUMOR (T)
TX Primary tumor cannot be assessed
T0 No evidence of primary tumor
T1 Solitary tumor without vascular invasion
T2 Solitary tumor with vascular invasion or multiple tumors none more than 5 cm
T3a Multiple tumors more than 5 cm
T3b Single tumor or multiple tumors of any size involving a major branch of the portal vein or hepatic vein
T4 Tumor(s) with direct invasion of adjacent organs other than the gallbladder or with perforation of visceral peritoneum

REGIONAL LYMPH NODES (N)
NX Regional lymph nodes cannot be assessed
N0 No regional lymph node metastasis
N1 Regional lymph node metastasis

DISTANT METASTASIS (M)
M0 No distant metastasis (no pathologic M0; use clinical M to complete stage group)
M1 Distant metastasis

Stage Grouping
Stage I T1 N0 M0
Stage II T2 N0 M0
Stage IIIA T3a N0 M
Stage IIIB T3b N0 M0
Stage IIIC T4 N0 M0
Stage IVA any T N1 M0
Stage IVB any T any N M1

CLIP Scoring System

	Score		
	0	1	2
Child-Pugh	A	B	C
Tumor morphology	Uninodular and extension ≤50%	Multinodular and extension ≤50%	Massive or extension >50%
AFP（ng/ml）	<400	>400	
Portal vein thrombosis	No	Yes	

[1] The CLIP score should be documented for all patients with HCC, while AJCC staging only for HCC patients underwent resection.

FEMH 化學治療處方參考集

【Sorafenib】
Sorafenib 400mg bid po, continuous

【Bevacizumab plus Erlotinib】
Bevacizumab 10mg/kg iv drip 2hrs, every 2 weeks
Erlotinib 150mg/d, po, continuous

【High-dose Tamoxifen plus Doxorubicin】
Tamoxifen 150 mg/m^2, PO, in divided dose, D1~D7
Doxorubicin 50~60 mg/m^2, IV, 24hrs, D4
Repeated cycles every 3~4 weeks

【Thalidomide ± UFUR】
Tgafur/uracil (UFUR) 125 mg/m^2 (based on tegafur), bid po
Thalidomide 100mg po bid.
During the treatment, must be take study drugs continuously.

【Doxorubicin】
Doxorubicin 40~60 mg/m^2, IV, 1~24hrs, D1,
Repeated cycles every3~4weeks.

【Soraferib plus Doxorubicin】
Soraferib 400 mg, bid po, continuous
Doxorubicin 40~60 mg/m^2, IV, 2hrs, D1,every3~4weeks

【FOLFOX】
Oxaliplation 85 mg/m^2, IV, 2hrs
Leucovorin 400 mg/m^2 in N/S 100ml IV drip 2hrs, concomitant with Oxaliplatin, then
5-FU 400 mg/m^2 in N/S 100ml IV drip 5 mins, followed by,
5-FU 2400 mg/m^2 in N/S 500ml IV drip 46 hrs
Every 2 weeks for a total of 24 weeks

【Modified FOLFOX at FEMH】
Oxaliplatin 85 mg/m^2 in D5W 250ml IV drip 2 hrs, followed by
[5-FU 2000-2600 mg/m^2 + Leucovorin 300-400mg/m2] in N/S 500ml IV drip 46 hrs, D1
Every 2 weeks for a total of 24 weeks

【XELOX】
Oxaliplatin 130 mg/m^2, IV, 2hrs, D1
Capecitabine 1000 mg/m^2,twice daily,po,D1~D4 every 3 weeks

References:

1. *N Engl J Med 2008;359:378-90*
2. *J Clin Oncol 2009; 27: 843-50*
3. *Hepatogastroenterology. 1998; 45:1955-60*
4. *JAMA 2010;304:2154-60*
5. *Invest New Drugs 2012;30:376-81*
6. *Br J Cancer 2007;97:862*

Updated on 2015-11-10

HCC-4頁 依據NCCN Clinical Practice Guidelines in Oncology- Hepatobiliary cancers V.2.2015修訂，Locoregional therapy選項： Ablation 、 TACE及 Exterially-beam radiation therapy (conformal or stereotactic) (category 2B) 位置上移

HCC-8頁 BCLC期別摘錄規則依據 行政院衛生署國民健康局 書函 (發文字號:國健癌字第1000302045號)，台灣癌症登記中心函稿2015/3/23更新

HCC-10頁 本院HCC 化學治療處方參考集由VS鄧仲仁醫師Review文獻後修訂。

Updated on 2014-11-11

依據NCCN Clinical Practice Guidelines in Oncology- Hepatobiliary cancers V.2.2014修訂

HCC-4頁 增加Locoregional therapy選項： Ablation 、 TACE及 Exterially-beam radiation therapy (conformal or stereotactic) (category 2B)

HCC-4頁 AFP, ~~if initially elevated~~, every 3 mo for 2 y, then every 6-12 mo [8]，修改為 AFP, every 3 mo for 2 y, then every 6-12 mo [8]

HCC-5頁 Metastatic HCC增加Consider biopsy to confirm metastatic disease

HCC-10頁本院HCC 化學治療處方參考集由VS鄧仲仁醫師Review文獻後修訂。

Updated on 2013-12-24

加入AASLD HCC practice guidelines. Hepatology, Vol. 53, No. 3, 2011修訂

HCC-4頁 參照AASLD HCC practice guidelines ，加入BLCL期別及建議治療選項。此外，增加Sorafenib 健保條件: Ⅰ.肝外轉移（遠端轉移或肝外淋巴結侵犯）的Child-Pugh A class患者。 Ⅱ.大血管侵犯（腫瘤侵犯主門靜脈或侵犯左/右靜脈第一分支）的Child-Pugh A class患者。

HCC-10頁 由VS鄧仲仁醫師，Review文獻後，修訂本院HCC 化學治療處方參考集。
加入【Soraferib plus Doxorubicin】、【FOLFOX】、【Modified FOLFOX at FEMH】、【XELOX】。
加入References：
JAMA 2010;304:2154-60
Invest New Drugs 2012;30:376-81
Br J Cancer 2007;97:862

Updated on 2012-06-26

HCC-2頁 參考NCCN HCC Guidelines v1.2012及國民健康局核心測量指標(2012)內容之肝癌共識診斷標準，CT修訂為3-phase CT，影像檢查增加Angiography選項。Tumor size > 2 cm ，應至少有一項典型動態影像 ，故修訂為1 Classic enhancement **&** AFP > 200 ng/ML or HBsAg or HCV(+) or Liver cirrhosis。

HCC-3頁 參照NCCN HCC Guidelines v1.2012，WORK-UP項目刪除LDH。

HCC-4頁 治療後的追蹤，參照NCCN HCC Guidelines v1.2012 並配合國民健康局核心測量指標(2012)內容，影像學檢查於2年內，原本每3-6 個月一次修訂為每3個月一次 ；治療2年後，原本每年一次修訂為每6-12個月一次。AFP的追蹤，治療2年後，原本每6個月一次修訂為每6-12個月一次。

Updated on 2011-07-12

HCC-2頁 參考NCCN Hepatobiliary Cancers Guidelines 2011v1及國民健康局核心測量指標(100/02/15修訂)內容之肝癌共識診斷標準，依據Tumor size建議影像學檢查、血清或做Biopsy。註腳加入：若病人一發現即為end stage HCC，選擇supportive / hospice care，在診斷期不強制CT or MR or angiography。

HCC-3頁 Staging work-up前面的文字敘述改與NCCN Guidelines一致：「HCC confirmed」。刪除與HCC-2頁重複的部分，合併WORK-UP項目。

HCC-4頁 Liver reserve (Child A或Child A)，加入病人年齡、performance status和with/ without comorbidity 的考量，治療選項修訂為Resection or Ablation or TACE。 此外，Anatomically Unresectable或Metastatic HCC，增加hospice care。

Updated on 2010-08-17~2010-08-31

HCC-1頁 下方註記處，high risk patient的範圍增加Family history。

Clinical presentation增加「Incidental liver mass nodule or nodule found during screning」、「Liver mass suspicious for hepatocellular carcinoma (HCC)」兩種狀況的路徑說明。

HCC-2頁 Imaging: CT / angiography修改為CT or angiography or MR。

HCC-3頁 Staging work-up前面加入「HCC」。

HCC-4頁

1.Liver reserve和comorbidity，文字敘述改為Consider Liver reserve、Consider comorbidity較為恰當。

2.為表現治療方式的優先次序，Ablation 改在TACE上方。

3.將國民健康局99年度核心測量指標內容列於下方的註記項目，提供 臨床醫師參考。

Updated on 2010-08-17~2010-08-31

HCC-5頁

1. Metastatic HCC的Options，增加UFUR (自 費)的選項。
2. Radiotherapy刪除for symptomatic relief。
3. Metastatic HCC的Options，增加TACE的選項。
4. Recurrence的image，增加MR(optional)。

HCC-7頁

1. Criteria for TACE，Child A and B改為Adequate liver reserve。
2. Criteria for conformal radiotherapy，Child A and B改為Adequate liver reserve。

HCC-8頁 Staging內容依據AJCC 7th Ed.。

Updated on 2009-11-10~2009-11-24

HCC-1頁 新版加上：high risk的病人考慮作tri-phase CT， high risk patient包含： B、C 肝carrier ，cirrhosis liver，progressive elevation的AFP。

HCC-2頁 Tri-phase CT或angiography，這兩個取一個，如果有classic (typical)的enhance，就當作是clinical diagnosis，如果沒有就進行biopsy。

HCC-4頁 TAE改成TACE。加入UCSF guideline的Criteria for liver transplant。假如病人有符合transplant的criteria，family裡面可能有potential life donor的話，可以在比較早的階段跟他討論有關transplant的事情。

HCC-7頁 TAE改成TACE。

Updated on 2009-11-10~2009-11-24

NCCN-1頁 台灣為肝癌盛行地區， abnormal or rising AFP 移到US前，並加上high risk的病人考慮作tri-phase CT ，註記說明 high risk patient包含：B、C 肝carrier，cirrhosis liver，持續昇高的AFP 。

NCCN-2頁(1)簡化(2)本院沒有contrast sona，故不適用，修改為tri-phase CT或angiography，如果有typical的enhancement，就當作是clinical diagnosis，如果沒有就進行biopsy。

NCCN-4頁(1)依據實證研究已證實肝臟移植對HCC存活的助益，將Liver Transplant拉到比較早的階段，如果家屬中有合適的活體捐贈者，就可以跟病人及家屬作這個討論。(2)國內目前採用 UCSF guideline的criteria for liver transplant。

Updated on 2008-2-21

Sorafenib in

a. Metastatic HCC (HCC-5頁)

b. Unresectable HCC which TACE is not feasible (HCC-4頁)

重大診療事件之定義(基準3.5)

(1) 輔助性化療或根治性放療三個月(90天)內造成死亡之個案。(2011.1.20醫療組會議)

(2) 根治性手術30天內死亡之個案。

(3) 明顯違反院內自訂之診療指引，影響病人安全或預後者。

Intra 癌症診療臨床指引位置

癌症診療指引 - Windows Internet Explorer

亞東紀念醫院員工專區

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AJCC TNM Cancer Staging Forms[7th Ed – 2010]

癌別	分癌	診療指引	放射治療指引	化療處方集	其它
頭頸癌	口腔癌	（頭頸癌）			
	鼻咽癌				
食道癌					
乳癌					
肝癌					BCLC分期