乳癌診療指引

乳癌多專科團隊

2005 年05 月制定 ~2021 年12 月30 日修訂

目錄

指引修訂摘要-2021

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***Table 3.* Clinical Prognostic Stage**

Clinical Prognostic Stage applies to ALL patients with breast cancer for clinical classification and staging. It uses clinical tumor (T), node (N) and metastases (M) information based on history, physical examination, any imaging performed (not necessary for clinical staging) and relevant biopsies. Genomic profile information is not included in Clinical Prognostic Stage as pathologic information from surgery is necessary to ascertain the prognosis using these tools.

TNM	Grade	HER2	ER	PR	Stage
Tis N0 M0	Any	Any	Any	Any	0
T1* N0 M0 T0 N1mi M0 T1* N1mi M0	G1	Positive	Positive	Positive	IA
				Negative	
			Negative	Positive	
				Negative	
		Negative	Positive	Positive	
				Negative	
			Negative	Positive	
				Negative	IB
	G2	Positive	Positive	Positive	IA
				Negative	
			Negative	Positive	
				Negative	
		Negative	Positive	Positive	
				Negative	
			Negative	Positive	
				Negative	IB
	G3	Positive	Positive	Positive	IA
				Negative	
			Negative	Positive	
				Negative	
		Negative	Positive	Positive	IB
				Negative	
			Negative	Positive	
				Negative	

TNM	Grade	HER2	ER	PR	Stage
T0 N1** M0 T1* N1** M0 T2 N0 M0	G1	Positive	Positive	Positive	IB
				Negative	IIA
			Negative	Positive	
				Negative	
		Negative	Positive	Positive	IB
				Negative	IIA
			Negative	Positive	
				Negative	
	G2	Positive	Positive	Positive	IB
				Negative	IIA
			Negative	Positive	
				Negative	
		Negative	Positive	Positive	IB
				Negative	IIA
			Negative	Positive	
				Negative	IIB
	G3	Positive	Positive	Positive	IB
				Negative	IIA
			Negative	Positive	
				Negative	
		Negative	Positive	Positive	IIB
				Negative	
			Negative	Positive	
				Negative	

Continued

*T1 includes T1mi.

**N1 does not include N1mi. T1 N1mi M0 and T0 N1mi M0 cancers are included for prognostic staging with T1 N0 M0 cancers of the same prognostic factor status.

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Table 3. **Clinical Prognostic Stage (continued)**

TNM	Grade	HER2	ER	PR	Stage
T2 N1*** M0 T3 N0 M0	G1	Positive	Positive	Positive	IB
				Negative	IIA
			Negative	Positive	
				Negative	IIB
		Negative	Positive	Positive	IIA
				Negative	IIB
			Negative	Positive	
				Negative	
	G2	Positive	Positive	Positive	IB
				Negative	IIA
			Negative	Positive	
				Negative	IIB
		Negative	Positive	Positive	IIA
				Negative	IIB
			Negative	Positive	
				Negative	IIIB
	G3	Positive	Positive	Positive	IB
				Negative	IIB
			Negative	Positive	
				Negative	
		Negative	Positive	Positive	IIIA
				Negative	IIIB
			Negative	Positive	
				Negative	IIIB

TNM	Grade	HER2	ER	PR	Stage
T0 N2 M0 T1* N2 M0 T2 N2 M0 T3 N1*** M0 T3 N2 M0	G1	Positive	Positive	Positive	IIA
				Negative	IIIA
			Negative	Positive	
				Negative	
		Negative	Positive	Positive	IIA
				Negative	IIIA
			Negative	Positive	
				Negative	IIIB
	G2	Positive	Positive	Positive	IIA
				Negative	IIIA
			Negative	Positive	
				Negative	
		Negative	Positive	Positive	IIA
				Negative	IIIA
			Negative	Positive	
				Negative	IIIB
	G3	Positive	Positive	Positive	IIB
				Negative	IIIA
			Negative	Positive	
				Negative	
		Negative	Positive	Positive	
				Negative	IIIB
			Negative	Positive	
				Negative	IIIC

Continued

*T1 Includes T1mi
***N1 includes N1mi. T2, T3, and T4 cancers and N1mi are included for prognostic staging with T2 N1, T3 N1 and T4 N1, respectively.

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***Table 3.* Clinical Prognostic Stage (continued)**

TNM	Grade	HER2	ER	PR	Stage
T4 N0 M0 T4 N1*** M0 T4 N2 M0 Any T N3 M0	G1	Positive	Positive	Positive	IIIA
				Negative	IIIB
			Negative	Positive	
				Negative	
		Negative	Positive	Positive	
				Negative	
			Negative	Positive	
				Negative	IIIC
	G2	Positive	Positive	Positive	IIIA
				Negative	IIIB
			Negative	Positive	
				Negative	
		Negative	Positive	Positive	
				Negative	
			Negative	Positive	
				Negative	IIIC
	G3	Positive	Positive	Positive	IIIB
				Negative	
			Negative	Positive	
				Negative	
		Negative	Positive	Positive	IIIC
				Negative	
			Negative	Positive	
				Negative	
Any T Any N M1	Any	Any	Any	Any	IV

Notes.

1. Because N1mi categorization requires evaluation of the entire node, and cannot be assigned on the basis of an FNA or core biopsy, N1mi can only be used with Clinical Prognostic Staging when clinical staging is based on a resected lymph node in the absence of resection of the primary cancer, such as the situation where sentinel node biopsy is performed prior to receipt of neoadjuvant chemotherapy or endocrine therapy.
2. For cases with lymph node involvement with no evidence of primary tumor (e.g. T0 N1, etc.) or with breast ductal carcinoma *in situ* (e.g. Tis N1, etc.), the grade, HER2, ER, and PR information from the tumor in the lymph node should be used for assigning stage group.
3. For cases where HER2 is determined to be "equivocal" by ISH (FISH or CISH) testing under the 2013 ASCO/CAP HER2 testing guidelines, the HER2 "negative" category should be used for staging in the Clinical Prognostic Stage Group.
4. The prognostic value of these Prognostic Stage Groups is based on populations of persons with breast cancer that have been offered and mostly treated with appropriate endocrine and/or systemic chemotherapy (including anti-HER2 therapy).

Continued

***N1 includes N1mi. T2, T3, and T4 cancers and N1mi are included for prognostic staging with T2 N1, T3 N1 and T4 N1, respectively.

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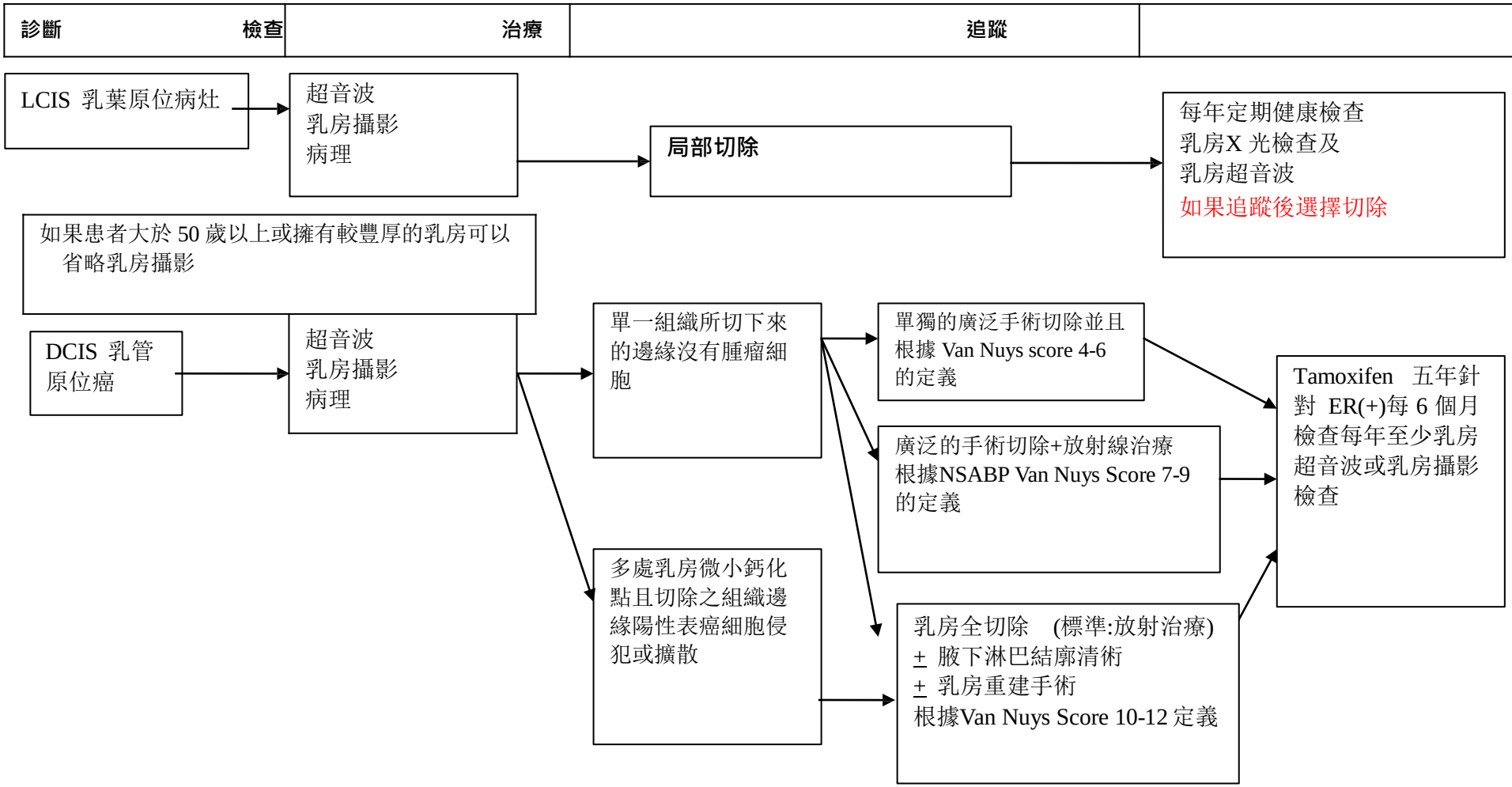
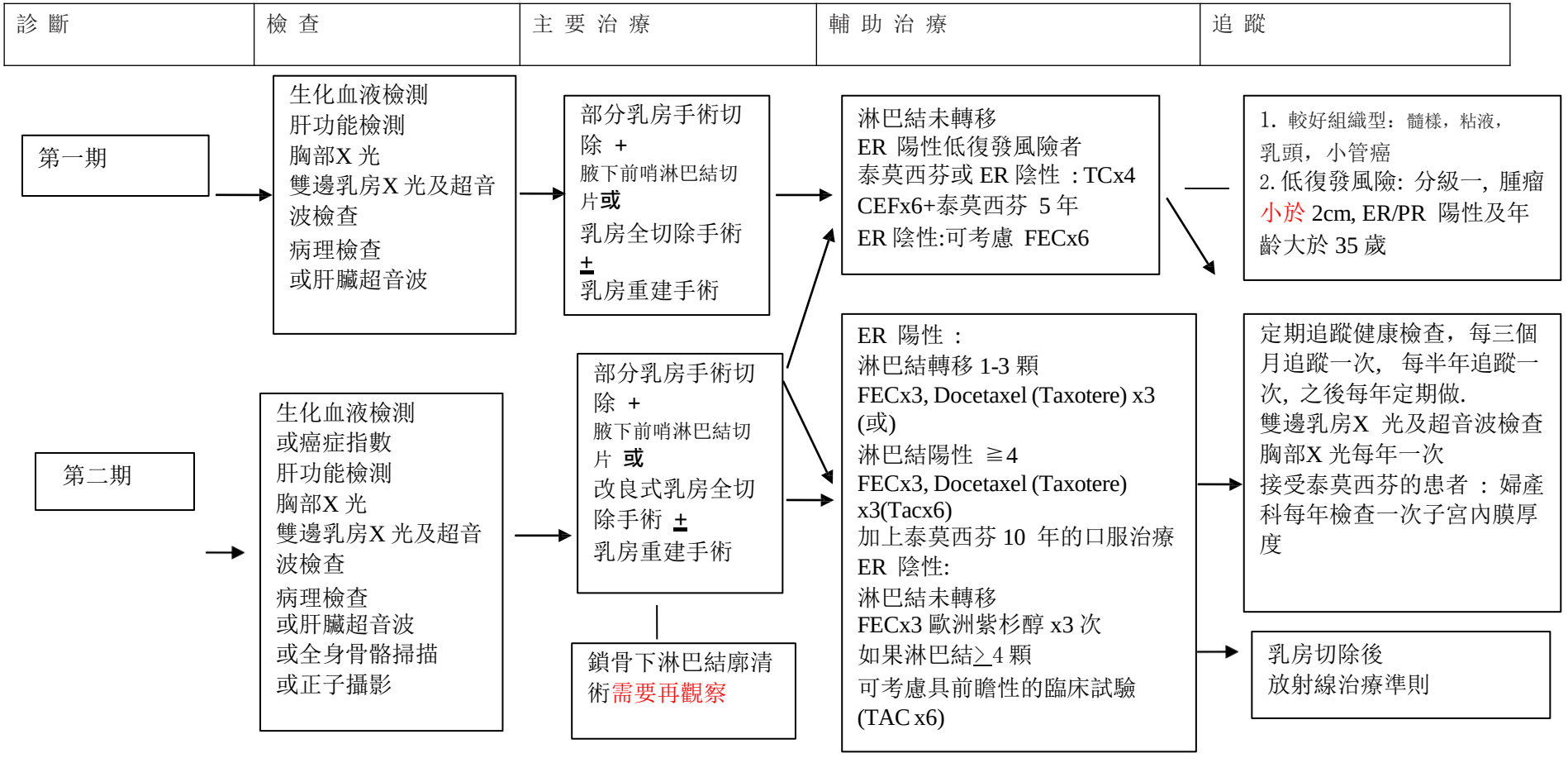
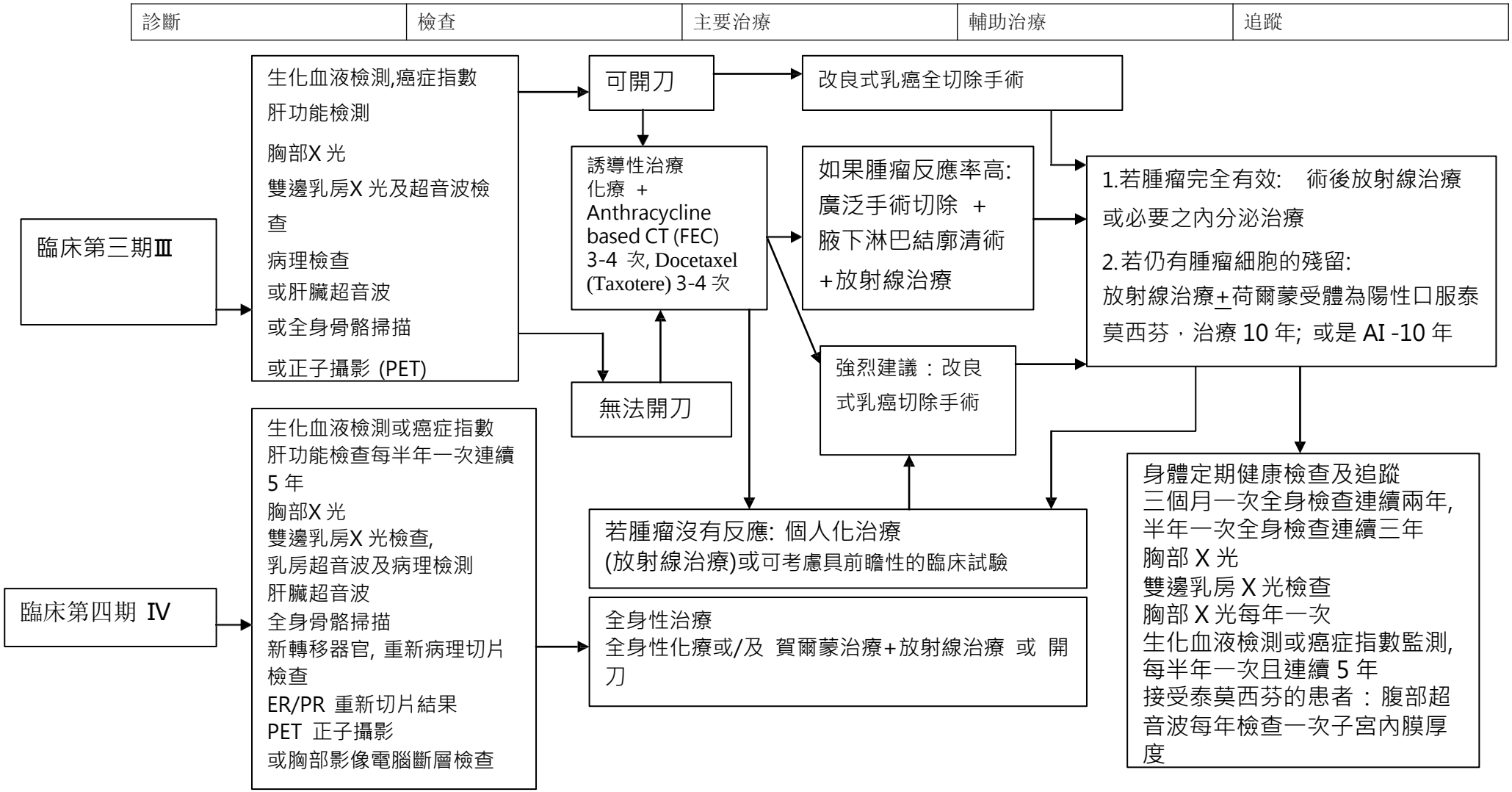

診斷 檢查
治療
追蹤
LCIS 乳葉原位病灶
超音波
乳房攝影
病理
局部切除
每年定期健康檢查
乳房X 光檢查及
乳房超音波
如果追蹤後選擇切除
如果患者大於 50 歲以上或擁有較豐厚的乳房可以省略乳房攝影
DCIS 乳管原位癌
超音波
乳房攝影
病理
單一組織所切下來的邊緣沒有腫瘤細胞
單獨的廣泛手術切除並且根據 Van Nuys score 4-6 的定義
廣泛的手術切除+放射線治療根據NSABP Van Nuys Score 7-9 的定義
多處乳房微小鈣化點且切除之組織邊緣陽性表癌細胞侵犯或擴散
乳房全切除 (標準:放射治療)
± 腋下淋巴結廓清術
± 乳房重建手術
根據Van Nuys Score 10-12 定義
Tamoxifen 五年針對 ER(+)每 6 個月檢查每年至少乳房超音波或乳房攝影檢查

針對 Node(-)、Triple-negative 之乳癌病患，腫瘤達 T1b 以上者，可以考慮給予輔助性化療(2016/6/4 台灣乳房醫學會乳癌治療共識結果)

1. 針對 Triple-negative 且帶有 BRCA mutation 的乳癌患者，可以考慮給予輔助性 platinum 化療(2016/6/4 台灣乳房醫學會乳癌治療共識結果)
2. ER(-)、HER-2(+)、Node(-) 之乳癌病患，腫瘤大小 T1b 或以上應該建議使用 Trastuzumab (Herceptin)加化療(2016/6/4 台灣乳房醫學會乳癌治療共識結果)





1. ER(+)、HER-2(+)、Node(-) 之乳癌病患，腫瘤大小 T1c 或以上應該建議使用 Herceptin 加化療；T1b 在某些情形下可以考慮(2016/6/4 台灣乳房醫學會乳癌治療共識結果)
2. ER(-)、HER-2(+)、Node(-) 之乳癌病患，若使用 Trastuzumab (Herceptin) 和 Taxane，當腫瘤小於 1 公分時，可以考慮不用加上 Anthracycline(2016/6/4 台灣乳房醫學會治療共識結果)
3. ER(+)、HER-2(+)、Node(-) 之乳癌病患，若使用 Trastuzumab (Herceptin) 和 Taxane，當腫瘤小於 2 公分時，可以考慮不用加上 Anthracycline(2016/6/4 台灣乳房醫學會乳癌治療共識結果)

復發　　檢查	狀態	治療 Salvage Treatment

盡可能針對患者新復發的病灶，重新進行病理檢查

例如 ER/PR

生化血液檢測或癌症指數

全身骨骼掃描

胸部X 光

胸部斷層掃描針對新病灶

肝臟超音波

斷層掃描

或全身核磁共振(若患者有其他症狀發生的話)

乳房攝影 ± 乳房超音波

或正子攝影

僅局部復發 Locoregional recurrence lone

- 先前僅乳房保留手術 → 全部乳房切除 ± 全身性治療+放射線治療
- 先前乳房保留手術 → 全部乳房切除 ± 全身性治療
- 先前單側乳房全切除 → 儘可能再手術切除 + 放射線治療 ± 全身性治療

全身性多處轉移 Systemic recurrence

- ER/PR negative or symptomatic → 化學治療
- ER/PR positive with 骨,軟組織無症狀; 肺轉移 → 先使用三線內分泌治療 +CDK4/6 抑制劑或+MTOR 抑制劑
- 僅有單一肝, 腦, 肺轉移 病理骨折, 脊髓壓迫 → 考慮手術切除可行性
- 多處腦轉移, 病理骨折, 脊髓壓迫 → 放射線治療可行性
- 肋膜, 心包膜積水, 腦模轉移 → 局部或是化學治療

診斷 **診斷檢察**

1. **乳葉原位病灶切片確認** →
   1. 詢問病情
   2. 乳房攝影
   3. 乳房超音波
   4. 病理確診

   →
   1. 不作放射線治療
   2. 多發性乳葉特別討論
   3. 不考慮手術切緣問題

註：1.LCIS 部分，依新版 2013 NCCN 規範，針對多發性 LCIS 之四個末端乳葉侵犯，可被視為高危險浸潤性乳癌。
2. 2015/12/21 修正
3. 2018/12/19 修正
4. 2019/12/19 修正
5. 2020/12/19 修正

(原位癌)Ductal carcinoma in situ (DCIS)乳腺管內癌

診斷	診斷檢查	PRIMARY TREATMENT
乳腺管內癌 →	1. 病情詢問 2. 乳房攝影 3. 乳房超音波 4. 病理確認 5. ER , PR	→ 1. 乳房部分切除或乳房全切除 2. 必要時考慮腋下前哨淋巴結切片 3. 考慮放射線治療 4. 考慮內分泌治療

1. 2018 起乳腺管內癌手術之切除邊緣乾淨，可以不在進一步手術 (不要求範圍)

臨床期別		診斷檢查		
第1A,2A, 2B, **3A期**	→	1. 病史詢問 2. 血液檢查(CBC, 紅血球, 白血球, 血小板) 3. 乳房超音波 4. 乳房攝影檢查 5. 乳房核磁共振 6. 病理確認, ER, PR, Her2/neu, MIB-1 7. 腹部超音波 8. 骨骼掃描 (淋巴結轉移考慮) 9. 腦部核磁共振(視臨床機關症狀) 10. 正子檢查(中晚期乳癌考慮)	→	1. 乳房部分切除 2. 乳房全切除 3. 腋下前哨淋巴結切片 4. 乳房重建考慮

早期乳癌(第 1 期&第 2 期)如觸診, 未摸到腋下淋巴結應執行前哨淋巴切片，前哨淋巴切片結果如(-)，不應進行淋巴擴清。(2016/6/4 台灣乳房醫學會乳癌治療共識結果)

第一, IIA, IIB, 第三期(T3N1M0) 期, 局部治療

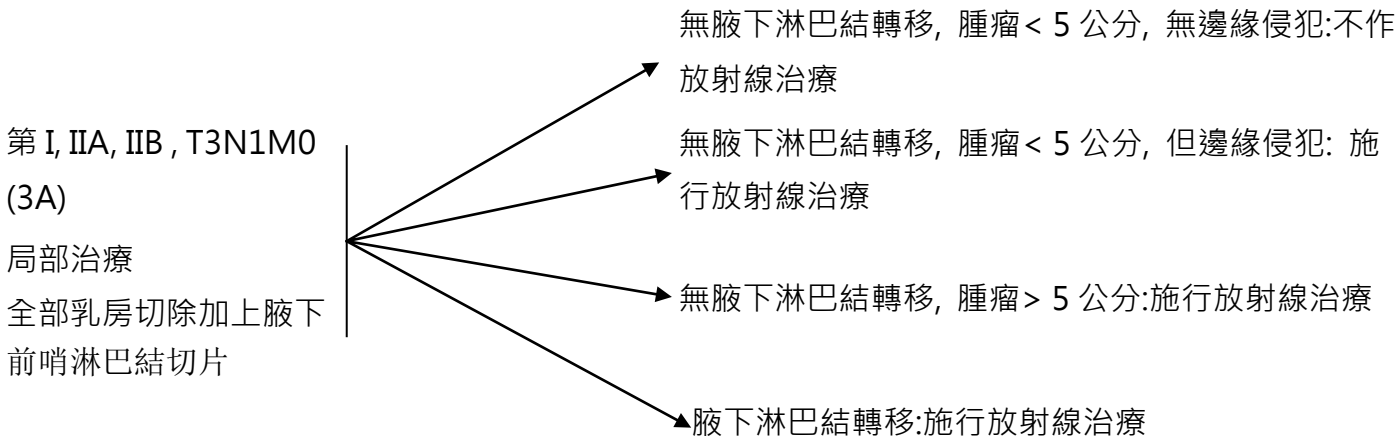
第 I, IIA, IIB , T3N1M0 (3A)
局部治療
部分乳房切除加上腋下前哨淋巴結切片

→ 無腋下淋巴結轉移, 術後放射線治療: 全部乳房

→ 腋下淋巴結轉移, 術後放射線治療
1. 全部乳房
2. 腫瘤部分加強照射
3. 同側腋窩
4. 同側鎖骨上區
5. 內乳淋巴結區域

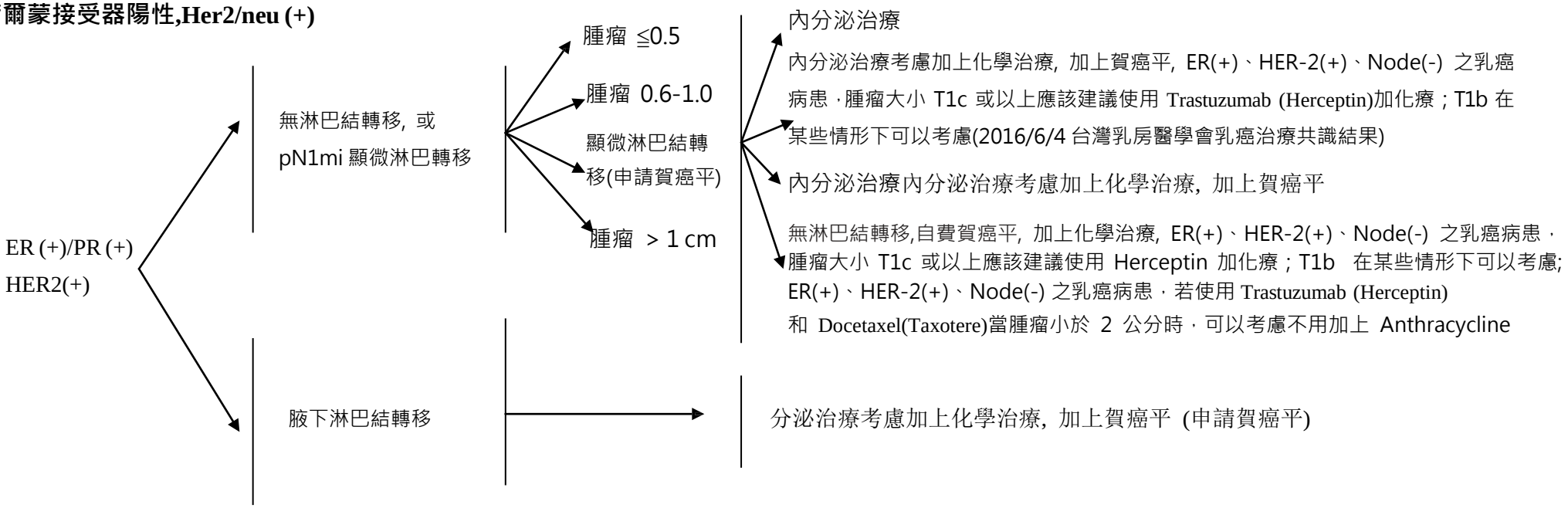
早期乳癌(第 1 期&第 2 期)如觸診, 未摸到腋下淋巴結應執行前哨淋巴切片，前哨淋巴切片結果如(-)，不應進行淋巴擴清。(2016/6/4 台灣乳房醫學會乳癌治療共識結果)

第 I, IIA, IIIB , T3N1M0 (3A) 局部治療



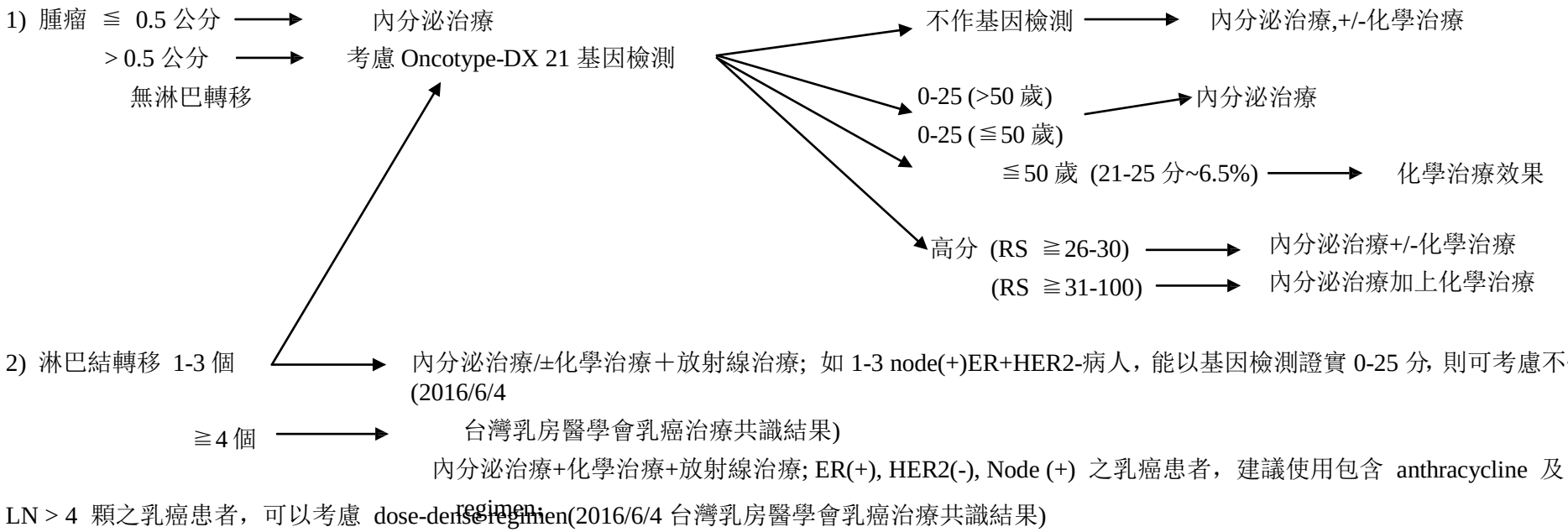
早期乳癌(第 1 期&第 2 期)如觸診, 未摸到腋下淋巴結應執行前哨淋巴切片，前哨淋巴切片結果如(-)，不應進行淋巴擴清。(2016/6/4 台灣乳房醫學會乳癌治療共識結果)

荷爾蒙接受器陽性,Her2/neu (+)



1. 不建議使用 GnRH analogue 治療所有停經前患者 (2016/6/4 台灣乳房醫學會乳癌治療共識結果)
2. 建議使用 GnRH analogue 治療停經前、接受過化療且卵巢功能恢復的患者（以 E2 FSH level 證明）(2016/6/4 台灣乳房醫學會乳癌治療共識結果)
3. 建議使用 GnRH analogue 治療停經前、腫瘤 T2 以上但沒接受化療的患者(2016/6/4 台灣乳房醫學會乳癌治療共識結果)
4. 可以考慮使用 GnRH analogue 治療停經前、高復發風險（ 包含有小於 40 歲、Node (+)、T1c 或以上且具備危險因子如 G3 或 genomic test high score 或 IHC4 定義為 intermediate risk 或以上）但未接受過化療的患者(2016/6/4 台灣乳房醫學會乳癌治療共識結果)
5. 建議使用 GnRH analogue 可合併使用 Tamoxifen 或 AI(2016/6/4 台灣乳房醫學會乳癌治療共識結果)
6. ER (+), node(+) 之乳癌病患，應該建議使用 10 年的賀爾蒙療法（tamoxifen 10 年或 AI 5 年加上 tamoxifen 5 年)；ER (+), node(-), 腫瘤 1 公分以上之乳癌病患可以考慮使用 10 年的賀爾蒙療法(2016/6/4 台灣乳房醫學會乳癌治療共識結果)
7. 停經後、ER/PR (+)、HER-2(-)、Node (+) 之乳癌患者，建議 AI 使用 5 年之後再給 5 年 tamoxifen(2016/6/4 台灣乳房醫學會乳癌治療共識結果)

荷爾蒙接受器陽性,Her2/neu (-)



LN > 4 顆之乳癌患者，可以考慮 dose-dense regimen(2016/6/4 台灣乳房醫學會乳癌治療共識結果)

1. 不建議使用 GnRH analogue 治療所有停經前患者 (2016/6/4 台灣乳房醫學會乳癌治療共識結果)
2. 建議使用 GnRH analogue 治療停經前、接受過化療且卵巢功能恢復的患者（以 E2 FSH level 證明）(2016/6/4 台灣乳房醫學會乳癌治療共識結果)
3. 建議使用 GnRH analogue 治療停經前、腫瘤 T2 以上但沒接受化療的患者(2016/6/4 台灣乳房醫學會乳癌治療共識結果)
4. 可以考慮使用 GnRH analogue 治療停經前、高復發風險（ 包含有小於 40 歲、Node (+)、T1c 或以上且具備危險因子如 G3 或 genomic test high score 或 IHC4

   定義為intermediate risk 或以上）但未接受過化療的患者(2016/6/4 台灣乳房醫學會乳癌治療共識結果)
5. 建議使用 GnRH analogue 可合併使用 Tamoxifen 或 AI(2016/6/4 台灣乳房醫學會乳癌治療共識結果)
6. ER (+), node(+) 之乳癌病患，應該建議使用 10 年的賀爾蒙療法（tamoxifen 10 年或 AI 5 年加上 tamoxifen 5 年)；ER (+), node(-), 腫瘤 1 公分以上之乳癌病患可以考慮使用 10 年的賀爾蒙療法(2016/6/4 台灣乳房醫學會乳癌治療共識結果)
7. 停經後、ER/PR(+)、HER-2(-)、Node(+) 之乳癌患者，建議 AI 使用 5 年之後再給 5 年 tamoxifen(2016/6/4 台灣乳房醫學會乳癌治療共識結果)
8. ER(+), HER2(-), Node (-) 之乳癌患者，建議使用 CE90 (A60C) 4 cycles /classical CMF。對於 anthracycline-based regimen 可以考慮不使用 5-FU(2016/6/4 台灣乳

Her2/neu 陽性　房醫學會乳癌治療共識結果

腫瘤≦0.5 公分 ⟶
1.不考慮化學治療
2.考慮作 Palitaxel+ Trastuzumab (Herceptin)/week x12 (2015 NEJM) (T1a, T1b, T1c, T2(≦3 公分)) 自費使 用太平洋紫杉醇, 賀癌平

> 0.5 公分 ⟶
化學治療加上賀癌平一年 (無淋巴結轉移, 自費使用賀癌平, 紫杉醇)
1.ER(-)、HER-2(+)、Node(-) 之乳癌病患，腫瘤大小 T1b 或以上應該建議使用 Herceptin 加化療 (2016/6/4 台灣乳房醫學會乳癌治療共識結果)
2.ER(-)、HER-2(+)、Node(-) 之乳癌病患，若使用 Trastuzumab (Herceptin)和 Taxane，當腫瘤小於 1 公分時， 可以考慮不用加上 Anthracycline (2016/6/4 台灣乳房醫學會乳癌治療共識結果)
3. 對臨床試驗以外可動手術的（不以保存乳房為目的）T2、N0、HER-2(+) 乳癌病患，可考慮提供 neoadjuvant therapy (2016/6/4 台灣乳房醫學會乳癌治療共識結果)
4. 術前化學治療加上雙標靶藥物治療(Tryphaena 研究)
5. 術後化學治療加上雙標靶藥物治療(Aphinity 研究)

✶ 淋巴結有轉移均考慮使用賀癌平加上化學治療

（全身性治療）浸潤性乳癌
三陰性乳癌(ER-,PR-,Her2/neu-)

三陰性乳癌 (ER- , PR-, Her2/neu -)

腫瘤≦0.5 公分 ⟶ 不作化學治療

>0.6~1.0 公分 ⟶ 考慮化學治療

>1.0 公分 ⟶ 化學治療 (F)ECx3, Docetaxel(Taxotere)x3

1. 針對 Node(-)、Triple-negative 之乳癌病患，腫瘤達 T1b 以上者，可以 考慮給予輔助性化療(2016/6/4 台灣乳房醫學會乳癌治療共識結果)
2. 針對 Triple-negative 且帶有 BRCA mutation 的乳癌患者，可以考慮給 予輔助性 platinum 化療(2016/6/4 台灣乳房醫學會乳癌治療共識結果)

✶ 無論淋巴結是否轉移, 均考慮加上化學治療

術前全身性治療評估 (不考慮先手術者) 2A, 2B, 3A (T2N0M0, T2N1M0, T3N0M0, T3N1M0)

CLINICAL STAGE

2A, 2B, 3A
(T2N0M0, T2N1M0,
T3N0M0, T3N1M0)

→

WORKUP

1. 病史詢問
2. 乳房超音波
3. 乳房攝影檢查
4. 病理評估 (ER, PR , Her2/neu, MIB-1)
5. 乳房核磁共振 (必要時選項)
6. 胸部 X-光片
7. 骨骼掃描 (淋巴腺轉移考慮)
8. 乳房保留手術評估
9. 同側腋下淋巴結評估, 穿刺切片

→

術前化學治療
四次 ((F)EC 為
主 x4)

→

考慮手術

NON-TRASTUZUMAB CONTAINING COMBINATIONS NEOADJUVANT REGIMENS

TC

- Docetaxel **(** 75 **)**mg/m2 IV day 1
- Cyclophosphamide 600 mg/m2 IV day 1

Cycled every 3weeks for 4 cycles

根據文獻，TC中的的“C”亦可使用Cisplatin 60 mg/m2 IVD day 1

Reference:

Jones S, Holmes F, O’Shaughnessey J, et al. Docetaxel with cyclophosphamide is associated with an overall survival benefit compared with doxorubicin and cyclophosphamide: 7-year follow-up of US Oncology Research trial 9735. J Clin Oncol 2009;27:1177-1183.

Modified CMF

- Cyclophosphamide 600 mg/m2 IV days 1
- Methotrexate 40 mg/m2 IV days 1
- 5-Fluorouracil 600 mg/m2 IV days 1

Repeat cycle every 21 days for 4 cycles

Reference:

Goldhirsch A, Colleoni M, Coates AS, et al: Adding adjuvant CMF chemotherapy to either radiotherapy or tamoxifen: are all CMFs alike? The International Breast Cancer Study Group (IBCSG). Ann Oncol 1998;9:489-93.

NON-TRASTUZUMAB CONTAINING COMBINATIONS NEOADJUVANT REGIMENS

(F)EC followed by docetaxel (各三次, 每21天一療程)

- (5-Fluorouracil 500 mg/m2 IV day 1)
- Epirubicin 100 mg/m2 IV day 1
- Cyclophosphamide 500 mg/m2 day

Cycled every 21 days for 3 cycles.
Followed by

- Docetaxel **(** 75 **)** mg/m2 day 1

Cycled every 21 days for 3 cycles.

Reference (參考文獻)

Roche H, Fumoleau P, Spielmann M, et al. Sequential adjuvant epirubicin-based and docetaxel chemotherapy for node-positive breast cancer patients: The FNCLCCPACS 001 trial. J Clin Oncol 2006; 24:5664-5671.

(F)EC (六次, 每21天一療程)

- (5-fluorouracil 500 mg/m2 IV day 1)
- Epirubicin 100 mg/m2 IV day 1
- Cyclophosphamide 500 mg/m2 IV day 1

Repeat cycle every 21 day for 6 cycles

Reference (參考文獻)

Roche H, Fumoleau P, Spielmann M, et al. Sequential adjuvant epirubicin-based and docetaxel chemotherapy for node-positive breast cancer patients: The FNCLCCPACS 001 trial. J Clin Oncol 2006; 24:5664-5671.

TRASTUZUMAB CONTAINING COMBINATIONS NEO ADJUVANT REGIMENS

1.HER-2(+) 之乳癌病患若想保留乳房，但腫瘤太大時，可考慮 neoadjuvant therapy
2.對臨床試驗以外可動手術的（不以保存乳房為目的）T2、N0、HER-2(+) 乳癌病患，可考慮提供 neoadjuvant therapy(2016/6/4台灣乳房醫學會乳癌治療共識結果)
3. HER-2(+) 之乳癌病患若想保留乳房，但腫瘤太大時，可考慮 neoadjuvant therapy
4. 對 Her-2(+) 之乳癌病患提供 neoadjuvant therapy 時，可以考慮加上Pertuzumab
5. Node(-)、腫瘤3公分、ER(-)、PR(-)、HER-2(3+) 之 45 歲乳癌病患，在 6個療程的 TCH 後沒有達到病理完全緩解 (pCR)，接下來可考慮anthracycline 4 個療程，接著使用 Herceptin 一年(2016/6/4台灣乳房醫學會乳癌治療共識結果)

TCH

- Docetaxel **(** 75 **)** mg/m2 IV day 1
- Carboplatin AUC 6 IV day 1

Cycled every 21 days for 6 cycles
With

- Trastuzumab 4 mg/kg wk 1

Followed by

- Trastuzumab 2 mg/kg for 17 wks Followed by
- Trastuzumab 6 mg/kg IV every 3 wks to complete 1 year of trastuzumab therapy. Cardiac monitoring at baseline, 3, 6, and 9 mo註：

TCH
原用藥組合為Docetaxel+ Carboplatin+ Trastuzumab
根據文獻，TCH中的的“C”亦可使用Cisplatin 60 mg/m2 IVD day 1

Reference:

Judith Hurley, Philomena Doliny, Isildinha Reis, Orlando Silva, Carmen Gomez-Fernandez, Pedro Velez,Giovanni Pauletti, Jodeen E. Powell, Mark D. Pegram, and Dennis J. Slamon. Docetaxel, Cisplatin, and Trastuzumab As Primary Systemic Therapy for Human Epidermal Growth Factor Receptor 2–Positive Locally Advanced Breast Cancer. JOURNAL OF CLINICAL ONCOLOGY.2006;24;1831-1839.

Tryphaena Trial

1. (Pertuzumab (自費) + trastuzumab + FECx3) , (Pertuzumab (自費) + trastuzumab + docetaxel x3) (各三次, 共六次, 每21天一療程)
2. FECx3 + (Pertuzumab (自費) + trastuzumab+ docetaxel x3) (各三次, 共六次, 每21天一療程)
3. FECx3 + (Trastuzumab+ docetaxel x3) (各三次, 共六次, 每21天一療程)

Reference (參考文獻)

Ann Oncology 2013 Sep;24(9):2278-84. doi: 10.1093/annonc/mdt182. Epub 2013 May 22.
Pertuzumab plus trastuzumab in combination with standard neoadjuvant anthracycline-containing and anthracycline-free chemotherapy regimens in patients with HER2-positive early breast cancer: a randomized phase II cardiac safety study (TRYPHAENA).

4. (F)EC followed by docetaxel + Cisplatin (各三次, 每21天一療程)目前榮總、和信、長庚皆使用此化學治療處方

❖(5. -Fluorouracil 500 mg/m2 IV day 1)
❖ Epirubicin 100 mg/m2 IV day 1
❖ Cyclophosphamide 500 mg/m2 day 1

Cycled every 21 days for 3 cycles.
Followed by

❖ Docetaxel (75) mg/m2 day 1
❖ Cisplatin 60 mg/m2 IVD day

Cycled every 21 days for 3 cycles.

Dose dense AC followed by paclitaxel+trastuzumab

- Doxorubicin 60mg/ m2 IV day 1
- Cyclophosphamide 600 MG/m2 IV day 1
- Cycled every 14 day for 4 cycles

followed by

- Paclitaxel 175 MG/m2 day 1

Cycled every 14 day for 4 cycles

With

- Trastuzumab 4 mg/kg IV with first dose of paclitaxel

followed by

- Trastuzumab 2 mg/kg IV weekly to complete 1 y of treatment.As an alternative, trastuzumab 6 mg/kg IV every 21 days may be used folloeing the completion of paclitaxel,and given to complete 1 y of trastuzumab treatment.

NON-TRASTUZUMAB CONTAINING COMBINATIONS ADJUVANT REGIMENS

TC (每三週一療程, 共四次)

- Docetaxel(75) mg/m2 IV day 1
- Cyclophosphamide 600 mg/m2 IV day 1

***TC中的的"C"亦可使用Cisplatin 60 mg/m2 IVD day 1**

註:須評估年紀大,心臟功能

Reference:

Jones S, Holmes F, O'Shaughnessey J, et al. Docetaxel with cyclophosphamide is associated with an overall survival benefit compared with doxorubicin and cyclophosphamide: 7-year follow-up of US Oncology Research trial 9735. J Clin Oncol 2009;27:1177-1183

(F)EC followed by docetaxel (各三次, 每21天一療程)

- (5-Fluorouracil 500 mg/m2 IV day 1)
- Epirubicin 100 mg/m2 IV day 1
- Cyclophosphamide 500 mg/m2 day 1

Followed by

- Docetaxel (75) mg/m2 day 1

Reference:

Roche H, Fumoleau P, Spielmann M, et al. Sequential adjuvant epirubicin-based and docetaxel chemotherapy for node-positive breast cancer patients: The FNCLCCPACS 001 trial. J Clin Oncol 2006; 24:5664-5671.

(F)EC (共六次, 每21天一療程)

- (5-fluorouracil 500 mg/m2 IV day 1)
- Epirubicin 100 mg/m2 IV day 1
- Cyclophosphamide 500 mg/m2 IV day 1

Reference:

Roche H, Fumoleau P, Spielmann M, et al. Sequential adjuvant epirubicin-based and docetaxel chemotherapy for node-positive breast cancer patients: The FNCLCCPACS 001 trial. J Clin Oncol 2006; 24:5664-5671.

TCH (共六次, 每 21 天一療程)

- Docetaxel **(** 75**)** mg/m2 IV day 1
- Carboplatin AUC 6 IV day 1
- Trastuzumab 4 mg/kg wk 1

  Followed by
- Trastuzumab 2 mg/kg for 17 wks

  Followed by
- Trastuzumab 6 mg/kg IV every 3 wks to complete 1 year of trastuzumab therapy. Cardiac monitoring at baseline, 3, 6, and 9 mo.

註：TCH原用藥組合為Docetaxel+ Carboplatin+ Trastuzumab
根據文獻，TCH中的的"C"亦可使用Cisplatin 60 mg/m2 IVD day 1

Reference:

Judith Hurley, Philomena Doliny, Isildinha Reis, Orlando Silva, Carmen Gomez-Fernandez, Pedro Velez,Giovanni Pauletti, Jodeen E. Powell, Mark D. Pegram, and Dennis J. Slamon. Docetaxel, Cisplatin, and Trastuzumab As Primary Systemic Therapy for Human Epidermal Growth Factor Receptor 2–Positive Locally Advanced Breast Cancer. JOURNAL OF CLINICAL ONCOLOGY.2006;24;1831-1839.

TRASTUZUMAB CONTAINING COMBINATIONS OTHER ADJUVANT REGIMENS:

AC followed by docetaxel with trastuzumab (各四次, 每21天一療程)

- Doxorubicin 60 mg/m2 IV day 1
- Cyclophosphamide 600 mg/m2 day 1
- Docetaxel **(** 75 **)**mg/m2 day 1

Cycled every 21 days for 4 cycles
With

- Trastuzumab 4 mg/kg IV wk one Followed by
- Trastuzumab 2 mg/kg IV weekly for 11 wks Followed by
- Trastuzumab 6 mg/kg every 21 days to complete 1 y of trastuzumab therapy

Cardiac monitoring at baseline, 3, 6, and 9 mo. (2015/12/21 修訂)

Reference:

Slamon D, Eiermann W, Robert N, et al. Adjuvant trastuzumab in HER2-positive breast cancer. N Engl J Med 2011;365:1273-1283.

Paclitaxel + trastuzumab 自費使用 (使用於T1a, T1b, T1c, T2 (≦3cm) 淋巴結(-) 或是僅一個淋巴結微小轉移, ≦3公分大小病灶) (2015/12/21 NEJM修訂)

- Paclitaxel 80 mg/m2 IV weekly for 12 weeks

With

- Trastuzumab 4 mg/kg IV with first dose of paclitaxel

Followed by

- Trastuzumab 2 mg/kg IV weekly to complete 1 y of treatment. As an alternative, trastuzumab 6 mg/kg IV every 21 days may be used following the completion of paclitaxel, and given to complete 1 y trastuzumab treatment.

Cardiac monitoring at baseline, 3, 6, and 9 mo.

Reference:

Tolaney S, Barry W, Dang C, et al. Adjuvant paclitaxel and trastuzumab for node-negative HER2-positive breast cancer. N Engl J Med 2015;372:134-141

TRASTUZUMAB CONTAINING COMBINATIONS OTHER ADJUVANT REGIMENS:

T-DM1(Kadcyla)

❖ T-DM1(Kadcyla) 3.6mg/kg every 3 weaks x14 【使用於術前含Trastuzmab (Herceptin)藥物化療,Katherine Trial】

內分泌治療

停經前

- Tamoxifen(Nolvadex) 一天兩次,一次一錠 10mg 口服使用, 或一天一次兩錠, 20mg 口服使用
- Leuprorelin(Leuplin) (Zoladex) 一月一次,一次 3.75mg 皮下注射 停

經後

- Tamoxifen(Nolvadex) 一天兩次,一次一錠 10mg 口服使用, 或一天一次兩錠, 20mg 口服使用
- Arimidex(Anastrozole) 一天一次,一次一錠 1mg 口服使用
- Femara(Letrozole) 一天一次,一次一錠 2.5mg 口服使用
- Aromasin 一天一次,一次一錠 25mg 口服使用

健保給付條文:

9.1.3.Letrozole：（88/11/1、90/10/1、92/3/1、97/11/1、98/11/1、99/9/1、102/8/1)

1. 接受抗動情激素治療失敗的自然或人工停經後之末期乳癌病人之治療、停經後之局部晚期或轉移性乳癌婦女患者之第一線治療用藥。

2. 停經後且荷爾蒙接受體呈陽性，有淋巴結轉移之乳癌病人，作為 tamoxifen 治療五年後的延伸治療，且不得與其他 aromatase inhibitor 併用。使用時需同時符合下列規定：（97/11/1）

⑴ 手術後大於等於 11 年且無復發者不得使用。

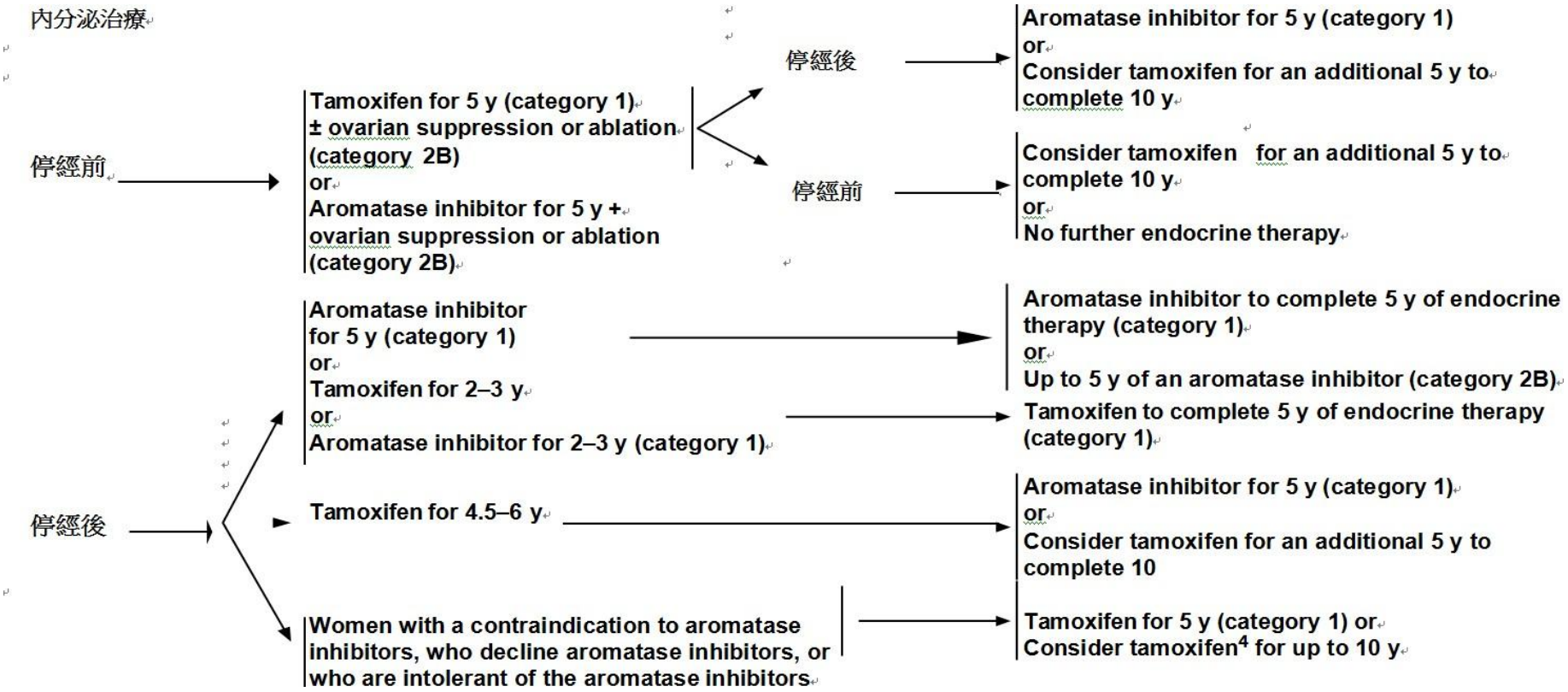
⑵ 每日最大劑量 2.5mg，使用不得超過四年。

3. 停經後且荷爾蒙接受體呈陽性之早期乳癌病人，經外科手術切除後之輔助治療，且不得與 tamoxifen 或其他 aromatase inhibitor 併用。使用時需同時符合下列規定：(98/11/1、99/9/1、102/8/1)

⑴ 每日最大劑量 2.5mg，使用不得超過五年；

⑵ 若由 tamoxifen 轉換使用本品，則使用期限合計不得超過 5 年。

4. 病歷上應詳細記載手術資料、病理報告(應包含 ER、PR 之檢測結果且無復發現象)及用藥紀錄(如 tamoxifen 使用五年證明)。(2015/12/21 修訂)



1. 建議使用 GnRH analogue 治療停經前、接受過化療且卵巢功能恢復的患者（以 E2 FSH level 證明）(2016/6/4 台灣乳房醫學會乳癌治療共識結果)
2. 建議使用 GnRH analogue 治療停經前、腫瘤 T2 以上但沒接受化療的患者(2016/6/4 台灣乳房醫學會乳癌治療共識結果)
3. 可以考慮使用 GnRH analogue 治療停經前、高復發風險（ 包含有小於 40 歲、Node (+)、T1c 或以上且具備危險因子如 G3 或 genomic test high score 或 IHC4 定義為 intermediate risk
   或以上）但未接受過化療的患者(2016/6/4 台灣乳房醫學會乳癌治療共識結果)
4. 建議使用 GnRH analogue 可合併使用 Tamoxifen 或 AI(2016/6/4 台灣乳房醫學會乳癌治療共識結果)
5. ER (+), node(+) 之乳癌病患，應該建議使用 10 年的賀爾蒙療法（tamoxifen 10 年或 AI 5 年加上 tamoxifen 5 年)；ER (+), node(-), 腫瘤 1 公分以上之乳癌病患可以考慮使用 10 年的賀爾蒙療法(2016/6/4 台灣乳房醫學會乳癌治療共識結果)
6. 停經後、ER/PR(+)、HER-2(-)、Node(+) 之乳癌患者，建議 AI 使用 5 年之後再給 5 年tamoxifen (2016/6/4台灣乳房醫學會乳癌治療共識結果

DOSING SCHEDULES FOR CHEMOTHERAPY REGIMENS FOR RECURRENT OR METASTATIC BREAST CANCER

Preferred single agents:

Anthracyclines:

Doxorubicin
- 60–75 mg/m² IV day 1, cycled every 21 days[1]

or
- 20 mg/m² IV day 1 weekly[2]

Pegylated liposomal encapsulated doxorubicin[3]
- 50 mg/m² IV day 1

Cycled every 28 days.

Taxanes:

Paclitaxel
- 175 mg/m² IV day 1

Cycled every 21 days.[4]

or
- 80 mg/m² IV day 1 weekly[5]

Antimetabolites:

Capecitabine[6]
- 1000–1250 mg/m² PO twice daily days 1–14

Cycled every 21 days.

Gemcitabine[7]
- 800–1200 mg/m² IV days 1, 8, and 15

Cycled every 28 days.

Other microtubule inhibitors:

Vinorelbine[8]
- 25 mg/m² IV day 1 weekly

Eribulin[9]
- 1.4 mg/m² IV days 1 and 8

Cycled every 21 days.

Other single agents:

Cyclophosphamide[10]
- 50 mg PO daily on days 1–21

Cycled every 28 days.

Carboplatin[11]
- AUC 6 IV on day 1

Cycled every 21–28 days.

Docetaxel[12,13]
- 60-100 mg/m² IV day 1

Cycled every 21 days.

or
- 35 mg/m² IV weekly for 6 wks followed by a 2-week rest, then repeat[14]

Albumin-bound paclitaxel
- 100 mg/m² or 150 mg/m² IV days 1, 8, and 15

Cycled every 28 days.[15,16]

or
- 260 mg/m² IV

Cycled every 21 days.[15]

Cisplatin[17]
- 75 mg/m² IV on day 1

Cycled every 21 days.

Epirubicin[18]
- 60–90 mg/m² IV day 1

Cycled every 21 days.

Ixabepilone[19]
- 40 mg/m² IV day 1

Cycled every 21 days.

DOSING SCHEDULES FOR CHEMOTHERAPY REGIMENS FOR HER-2 POSITIVE RECURRENT OR METASTATIC BREAST CANCER

Preferred first-line agents for HER2-positive disease:

Pertuzumab + trastuzumab + docetaxel[30]
- Pertuzumab 840 mg IV day 1 followed by 420 mg IV
- Trastuzumab 8 mg/kg IV day 1 followed by 6 mg/kg IV
- Docetaxel 75–100 mg/m² IV day 1

Cycled every 21 days.

Pertuzumab + trastuzumab + paclitaxel[31]
- Pertuzumab 840 mg IV day 1 followed by 420 mg IV cycled every 21 days
- Trastuzumab
  - 4 mg/kg IV day 1 followed by 2 mg/kg IV weekly
    or
  - 8 mg/kg IV day 1 followed by 6 mg/kg IV cycled every 21 days[33]
- Paclitaxel 80 mg/m² IV day 1 weekly[31]
  or
- Paclitaxel 175 mg/m² day 1 cycled every 21 days

Other first-line agents for HER2-positive disease:

Paclitaxel/carboplatin + trastuzumab[32]
- Carboplatin AUC 6 IV day 1
- Paclitaxel 175 mg/m² IV day 1

Cycled every 21 days.
- Trastuzumab
  - 4 mg/kg IV day 1 followed by 2 mg/kg IV weekly
    or
  - 8 mg/kg IV day 1 followed by 6 mg/kg IV every 21 days[33]

Weekly paclitaxel/carboplatin + trastuzumab[34]
- Paclitaxel 80 mg/m² IV days 1, 8, & 15
- Carboplatin AUC 2 IV days 1, 8, & 15

Cycled every 28 days.
- Trastuzumab
  - 4 mg/kg IV day 1 followed by 2 mg/kg IV weekly
    or
  - 8 mg/kg IV day 1 followed by 6 mg/kg IV every 21 days[33]

Trastuzumab + paclitaxel
- Paclitaxel
  - 175 mg/m² IV day 1 cycled every 21 days[35]
    or
  - 80–90 mg/m² IV day 1 weekly[36]
- Trastuzumab
  - 4 mg/kg IV day 1 followed by 2 mg/kg IV weekly
    or
  - 8 mg/kg IV day 1 followed by 6 mg/kg IV every 21 days[33]

Trastuzumab + docetaxel
- Docetaxel
  - 80–100 mg/m² IV day 1 cycled every 21 days[37]
    or
  - 35 mg/m² IV days 1, 8, and 15 weekly[38]
- Trastuzumab
  - 4 mg/kg IV day 1 followed by 2 mg/kg IV weekly
    or
  - 8 mg/kg IV day 1 followed by 6 mg/kg IV every 21 days[33]

Trastuzumab + vinorelbine[39]
- Vinorelbine
  - 25 mg/m² IV day 1 weekly
    or
  - 30–35 mg/m² IV days 1 and 8

Cycled every 21 days.
- Trastuzumab
  - 4 mg/kg IV day 1 followed by 2 mg/kg IV weekly
    or
  - 8 mg/kg IV day 1 followed by 6 mg/kg IV every 21 days[33]

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INDICATIONS FOR POST-MASTECTOMY RADIOTHERAPY

1.skin involvement(skin nodule,ulceration, dermal lymphatic involvement)internal chain and supraclavicular fossa
2. pectoral fascia involvement
3. positive axillary lymph nodes≧1
4.positive or close surgical margin
5.Number of tumor ≥ 4
6. gross multicentric disease(tumor in more than one quadrant and at least 4cm by clinical or pathology)
7.axillary node 1-3 positive patient had 3 risk factors， nuclear grade 2 or 3,LVI(+),ESC(+),tumor>2cm(T2),age<40,ER(-)

BASIC REQUIREMENTS OF RADIOTHERAPY

*Radiation fields should include ipsilateral chest wall,mammary

*Excluding heart from radiation fields
*Central lung distance of the tangential fields<3cm
*No axillary irradiation if axillary clearance is adequate

病理診斷參考條件

*Exact tumor size and type of tumor
*Tumor histological and/or nuclear grade
*Marginal status (exact distance in mm)
*Status of lymphovascular permeation
*ER and PR study

Ductal carcinoma in situ with wide excision only

*Nuclear grade
*Status of tumor necrosis
*Tumor size
*Marginal status (exact distance in mm)
*ER/PR study

Invasive carcinoma with wide excision and axillary lymph node dissection or modified radical mastectomy

*Exact invasive tumor size and type of tumor
*Tumor histologic and/or nuclear grade
*Marginal status(exact distance in mm)
*Status of multifocality and multicentricity
*Presence of DCIS within the invasive tumor
*Presence of DCIS outside the main tumor
*Status of peritumoral LVI (defined as one high power distance from the general contours of the main tumor)
*Number of involved and total axillary lymph nodes with the largest size recorded,status of extranodal invasion， total number of axillary nodes examined should not be less than 10.
*If any involvement of skin
*ER， PR and Her-2-neu study

一、放射治療政策

1.Whole breast R/T or chest wall / Regional lymphatics

Conventional fractionation 45-50 Gy (1.8-2 Gy per fraction); hypofractionated 40 Gy in 15-16 fx. Additional 10-16 Gy dose is delivered to the surgical bed is recommended in patients at high risk for recurrence.

2.Partial breast R/T

APBI 34 Gy/10 fx/5 day 1 weak after operation

IORT 20 Gy/1 fx at operation

振興醫療財團法人振興醫院

熙雲正子影像中心

一、懷疑乳癌復發或有乳癌復發之臨床證據：

Tumor marker高、觸摸到腫塊，並經超音波或CT證實，或高危險群病患臨 床懷疑復發。

建議：

1. 有tumor marker、超音波或CT檢查結果者，可作「健保」全身PET/CT (RN26072)。
2. 懷疑復發，但無tumor marker、超音波或CT檢查結果者，可作「自費」 局部PET/CT (RN26073，胸部)。

二、 Local advanced breast cancer及inflammatory breast cancer （或臨床stage ⅡB以上）之分期

建議：

1. 有超音波或CT檢查結果者，可作「健保」全身PET/CT (RN26072)。
2. 無完整超音波及CT檢查結果者，可作「自費」局部PET/CT (RN26073，胸部)。

三、評估治療效果

1. 評估neoadjuvant chemotherapy效果

   建議：化療1-2 cycles後或三陰性乳癌2 cycles後，可作PET/CT。

   a. 如與第一次PET/CT相隔一個月以上，可作「健保」全身PET/CT (RN26072)。

   b. 如與第一次PET/CT相隔不到一個月，建議作「自費」局部PET/CT (RN26073，胸部)。

2. 早期評估hormonal therapy治療效果

   建議：在開始hormonal therapy 10天內，作PET/CT (觀察療效指標之metabolic flare)

   a. 如與第一次PET/CT相隔一個月以上，可作「健保」全身PET/CT (RN26072)。

   b. 如與第一次PET/CT相隔不到一個月，建議作「自費」局部PET/CT (RN26073，胸部)。

3. 評估轉移病灶之治療效果視需求可於治療中途或全程治療完成後一個月，作PET/CT。

   建議：

   a. 有tumor marker、超音波或CT檢查結果者，可作「健保」全身PET/CT (RN26072)。

   b. 無完整tumor marker、超音波或CT檢查結果者，或相隔前次PET/CT檢查不到一個月者，建議作「自費」局部PET/CT (RN26073，胸部)。

接受標靶治療或免疫治療，療程中及治療後，如每次PET/CT檢查相隔 一個月以上，可作「健保」全身PET/CT (RN26072)；如相隔未滿一個 月，建議作「自費」局部PET/CT (RN26073，胸部)。四、其他狀況

歡迎洽詢本中心 劉仁賢醫師 21400，5771。 溫馨叮嚀

1. 只要符合健保表列規定，若被剔退，院方不會罰扣款處理。

2.FDG PET/CT推廣期間，癌病患自費局部FDG PET/CT檢查（無其他保險支 持者），將以全身檢查優惠。

振興醫療財團法人振興醫院

熙雲正子影像中心

四、其他狀況

歡迎洽詢本中心 劉仁賢醫師 21400，5771。 溫馨叮嚀

1. 只要符合健保表列規定，若被剔退，院方不會罰扣款處理。
2. FDG PET/CT推廣期間，癌病患自費局部FDG PET/CT檢查（無其他保險支 持者），將以全身檢查優惠。
3. 健保FDG PET/CT癌病檢查，請開立全身掃描檢查。
4. 病患如有防癌保險，可考慮自費全身FDG PET/CT，不受健保條件約束。 如有任何問題，請不吝指正。

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附件

健保給付項目，依健保署99年6月1日公告之給付規定，適應症如下：

(一) 正子造影 — 全身

1. 乳癌、淋巴癌之分期、療效評估及懷疑復發或再分期。
2. 大腸癌、直腸癌、食道癌、頭頸部癌（不包含腦瘤）、原發性肺癌、黑 色素癌、甲狀腺癌及子宮頸癌，分期及懷疑復發或再分期。
   A. 分期：評估腫瘤之期別。
   B. 療效評估：評估腫瘤對治療之反應，擬改變治療方式時。
   C. 懷疑復發或再分期：使用於患者已接受一階段之正統治療後，偵測 疑似有復發或轉移及評估復發之程度（不得用於例行之追蹤檢查）。
   D. 以上各階段須符合：經電腦斷層、核磁共振、核子醫學掃瞄等檢查 仍無法分期者，或認定電腦斷層、核磁共振等檢查不足以提供足夠 資訊以供治療所需者，且須於病歷中說明施行正子造影之必要性理 由 。
   E. 配合腫瘤治療計畫者方得以正子造影作為療效評估項目，未有後續 積極處置之計畫者，不得施行。

(二)正子造影 — 局部

1. 存活心肌偵測：限LVEF ≦ 40%以下且以（或認定）傳統心肌斷層灌 注掃描無法做確切心肌存活者適用。
2. 癲癇病灶術前評估：持續且規則性服用三種(含)以上抗癲癇藥物治療≧ 一年，且近一年內平均每月有一次以上發作合併意識喪失者之術前評估。
3. 符合全身癌症掃描檢查適應，但只需作頭頸部、胸部或腹部局部造影。
4. 未符合健保給付規定者，可自費申請全身正子斷層掃描檢查（43,800元）或局部 正子斷層掃描檢查（26,500元）。