乳癌診療指引

每年修訂兩次　4 月及 10 月修訂

乳癌多專科團隊

2005 年 05 月制定　2009 年 07 月修訂　2010 年 08 月修訂

2011 年 12 月修訂　2012 年 09 月修訂　2012 年 11 月修訂

2013 年 03 月修定　2013 年 08 月修訂　2013 年 10 月修訂

2014 年 12 月修訂　2015 年 12 月修訂　2016 年 01 月修訂

2016 年 03 月修訂　2016 年 04 月修訂　2016 年 05 月修訂

2016 年 06 月修訂　2016 年 12 月修訂

內容

一、診療指引修訂共識

1. 依據乳癌多專科團隊會議討論決定(2016)。
2. 乳癌之期別，TNM 臨床檢查，超音波、乳房攝影、乳房核磁共振、骨骼掃描、正子檢查、電腦斷層，各不同檢查上註明所看見之臨床期別，於團隊會議中統一臨床或病理期別(2016)。
3. 考慮於慎選 T1，T2 乳癌施行乳房保留手術後，立即施行術中放射治療(唯屬於自費項目)(2013)。
4. 年齡超過 75-79 歲，T1N0、ER(+)，low-grade，partial mastectomy，可不需做放射線治療(2012)。
5. 年齡超過 70 歲以上，依照個別情形治療，依 NCCN，並未有明確詳細規範(2012)。

二、化療處方修定共識

1. 依癌症評鑑委員之建議，刪去不用之術前，術後化療處方(2015)。
2. 依癌症預評檢討會議 20130413，僅列出化療處方，依病情修飾劑量，並不需特別註明，不算另一處方(2013)。
3. 依據新版 2013 NCCN 規範刪去 TAC 、FAC、AC 之術前化療處方；加上 TC 術前化療處方(2013)。
4. 依據 2014.V3 版修訂於 Her2(+)，術前、轉移使用標靶藥物考慮同時 Pertuzumab + Trastuzumab 使用(2014,2016)。
5. 依據 2014.V3 版修訂於第一期低危險性族群 Her2(+)可選擇祇用 Paclitaxel + Trastuzumab 使用(2014)。
6. 化療藥物修改如下: (2015/12/21)

Her2 – Neoadjuvant

1. Dose-dense AC followed by paclitaxel :目前無使用此處方，刪除診療指引此治療處方。
2. AC followed by paclitaxel I :刪除診療指引此治療處方。

3.TC:標註自費及規範使用頻率為四次。
4.Modified CMF :刪除診療指引此治療處方。
5.AC followed by docetaxel :刪除診療指引此治療處方。
6.FEC followed by docetaxel : Docetaxel 標註自費。
7.FEC :確認使用頻率為 6 次。

Her2 + Neoadjuvant

1.AC followed by T chemotherapy with Trastuzumab: 2015/12/23 刪除此化療處方。
2.TCH :討論 TCH 中的的"C"改成 Cisplatin 是否能被接受，待標註 Carboplatin 需自費及若腋下淋巴結(-)T 也須自費。
12/23 已與蘇正熙主任討論，待刪除 Carboplatin 改 Cisplatin 並找出文獻佐證此治療處方。
3.T followed by FEC chemotherapy with trastuzumab: 刪除診療指引此治療處方。
4.Docetaxel + trastuzumab followed by FEC :保留此治療處方。
5.Chemotherapy followed by trastuzumab:保留此治療處方。
6.AC followed by docetaxel with trastuzumab:刪除診療指引此治療處方。
7.Pertuzumab + trastuzumab + docetaxel:NCCN 有此項處方,但 Docetaxel 劑量 75-100mg/m2 IV，後續待找到能佐證之並將劑量修改為 75 mg/m2 IV。
8.Pertuzumab + trastuzumab + paclitaxel : 刪除診療指引此治療處方。
9.Paclitaxel/carboplatin +trastuzumab : 刪除診療指引此治療處方。
10. Pertuzumab + trastuzumab + FECx3, → Pertuzumab + trastuzumab + Taxotere x3 增列
11.FECx3→Pertuzumab + trastuzumab + Taxotere x3 增列

Her2 - adjuvant

1.FAC :刪除診療指引此治療處方。
2.AC followed by paclitaxel : 刪除診療指引此治療處方。
3.TC :保留此治療處方，並標註適用的個案族群，如心臟功能不佳、年長 (4 cycle)

4.Modified CMF: 刪除診療指引此治療處方。
5.AC followed by docetaxel: 刪除診療指引此治療處方。
6.FEC followed by docetaxel :保留此治療處方。
7.FEC :補上使用 6cycle。

Her2 + adjuvant

1.AC followed by T chemotherapy with Trastuzumab-1: 刪除診療指引此治療處方。
2.TCH : Carboplatin 需標註自費、Trastuzumab 註明視淋巴結轉移與否決定是否自費。
3.Docetaxel + trastuzumab followed by FEC : 刪除診療指引此治療處方。
4.Chemotherapy followed by trastuzumab : 刪除診療指引此治療處方。
5.AC followed by docetaxel with trastuzumab :保留此治療處方。
6.Paclitaxel + trastuzumab:標註 Node(-)Low Risk 自費使用。
7.Pertuzumab + trastuzumab + docetaxel followed by FEC chemotherapy: 刪除診療指引此治療處方。
8.Pertuzumab + trastuzumab + Paclitaxel followed by FEC chemotherapy: 刪除診療指引此治療處方。

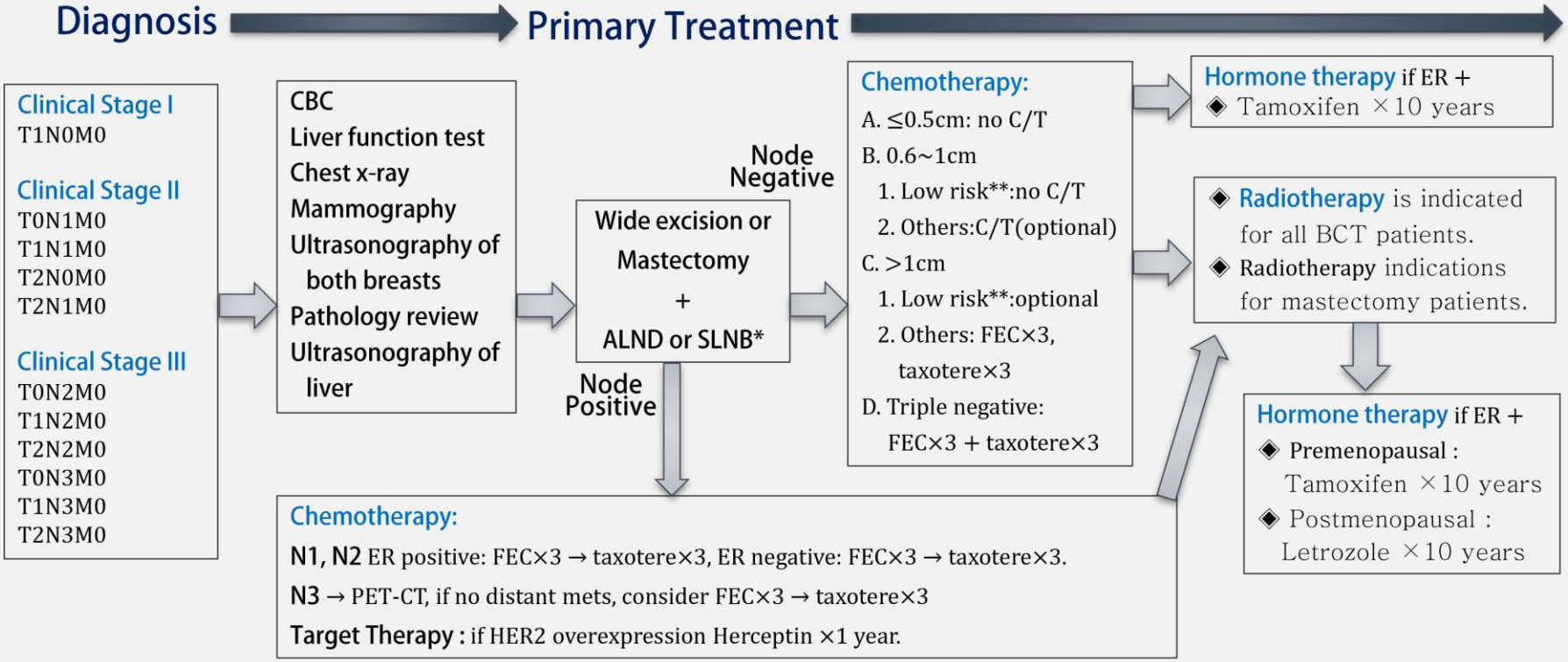
Metastatic 將目前院內診療指引列出的項目核對院內常用的處方予以保留。
2016/04/29 Docetaxel 確定劑量 75 mg/m^2 及增加 Neoadjuvant 處方"Modified CMF"。用於心臟功能不佳，不適於 anthracycline 者

2016/05/23 外院專家 (和信吳茂青醫師)乳癌治療指引修訂建議及乳癌治療各專科統整

2016/06/04 台灣乳房醫學會乳癌治療共識結果:
1.ER+Node-HER2- 病人如能以基因檢測證實 Low risk，則可考慮不做化療。
2. 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。
3. 不建議使用 GnRH analogue 治療所有停經前患者。
4. 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）

1. 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。
2. 建議使用 GnRH analogue 可合併使用 Tamoxifen 或 AI。
3. 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。
4. 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。
5. 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。
6. ER(+), HER2(-), Node (+) 之乳癌患者，建議使用包含 anthracycline 及 taxane 之 regimen； LN > 4 顆之乳癌患者，可以考慮 dose-dense regimen。
7. 如 1-3 node(+)ER+HER2-病人，能以基因檢測證實 Low risk，則可考慮不做化療(2016/6/4 台灣乳房醫學會乳癌治療共識結果)。
8. 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。
9. 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。
10. 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。
11. 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。
12. ER(-)、HER-2(+)、Node(-) 之乳癌病患，若使用 Herceptin 和 Taxane，當腫瘤小於 1 公分時，可以考慮不用加上 Anthracycline。
13. ER(+)、HER-2(+)、Node(-) 之乳癌病患，若使用 Herceptin 和 Taxane，當腫瘤小於 2 公分時，可以考慮不用加上 Anthracycline。
14. HER-2(+) 之乳癌病患若想保留乳房，但腫瘤太大時，可考慮 neoadjuvant therapy。
15. 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。
16. 對 Her-2(+) 之乳癌病患提供 neoadjuvant therapy 時，可以考慮加上 Pertuzumab 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。

Breast Cancer



*Criteria of sentinel lymph node biopsy (SLNB) : early breast cancer with clinically negative axillary lymph node. Axillary lymph node dissection (ALND) is recommended if SLN(+).

***Low Risk: 1. Tumor≤2cm, G1, ER+, HER-, no LVI, or 2. Favorable histology (≤3cm): typical medullary, mucinous, tubular carcinoma

#**Tamoxifen** as the drug of choice. If intolerable side effect, consider aromatase inhibitor.

1. TNM staging as AJCC 2010 7th ed.
2. Radiotherapy is indicated for all patient receiving breast conserving therapy (after chemotherapy).

診斷	檢查	治療	追蹤

LCIS 乳葉原位癌 → 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

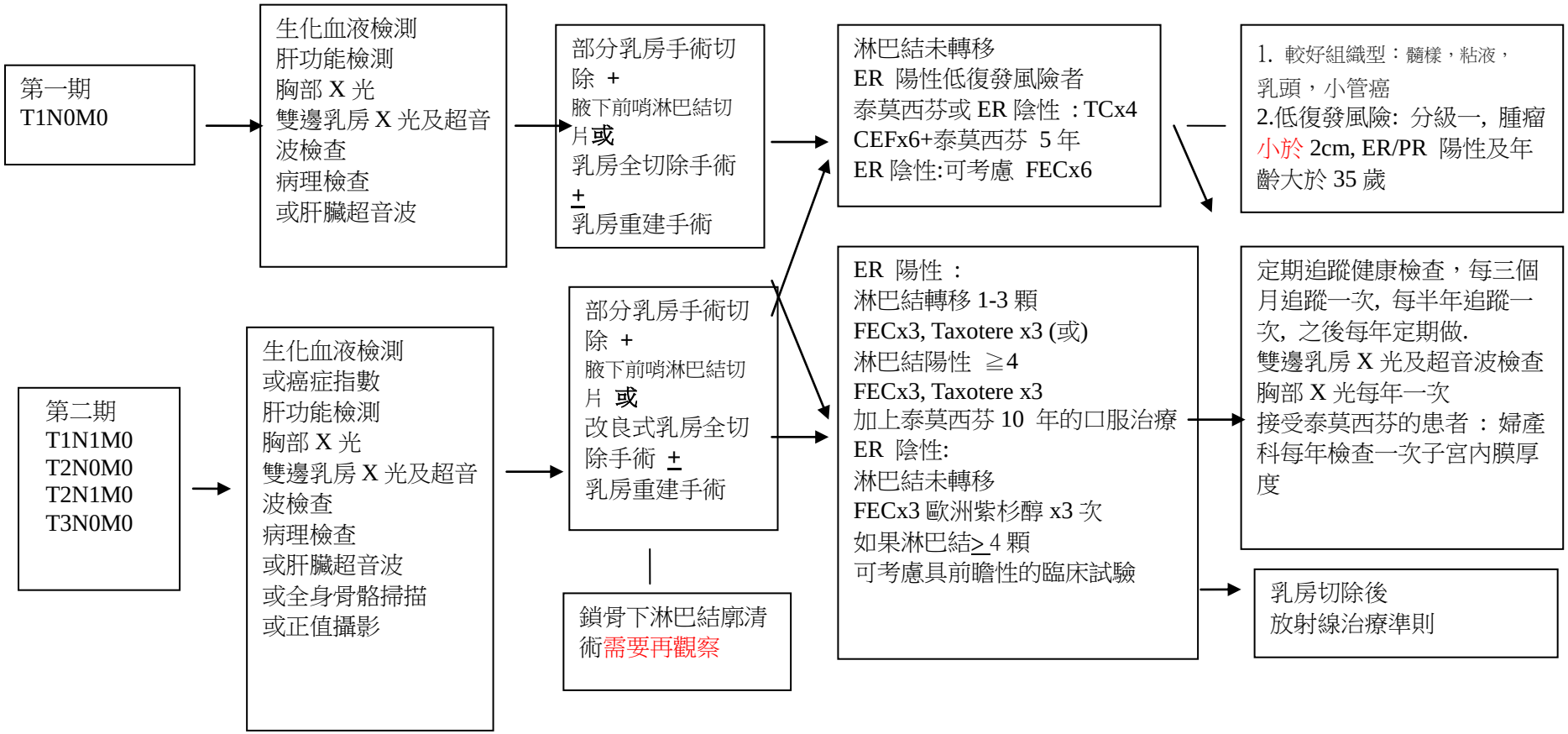
- 單一組織所切下來的邊緣沒有腫瘤細胞
  - 單獨的廣泛手術切除並且根據 Van Nuys score 4-6 的定義 → Tamoxifen 五年針對 ER(+)每 6 個月檢查每年至少乳房超音波或乳房攝影檢查
  - 廣泛的手術切除+放射線治療 根據 NSABP Van Nuys Score 7-9 的定義 → Tamoxifen 五年針對 ER(+)每 6 個月檢查每年至少乳房超音波或乳房攝影檢查
- 多處乳房微小鈣化點且切除之組織邊緣陽性表癌細胞侵犯或擴散 → 乳房全切除 (標準:放射治療) ± 腋下淋巴結廓清術 ± 乳房重建手術 根據 Van Nuys Score 10-12 定義 → 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

新版 Van Nuys 預後指數評估系統(VNPI)

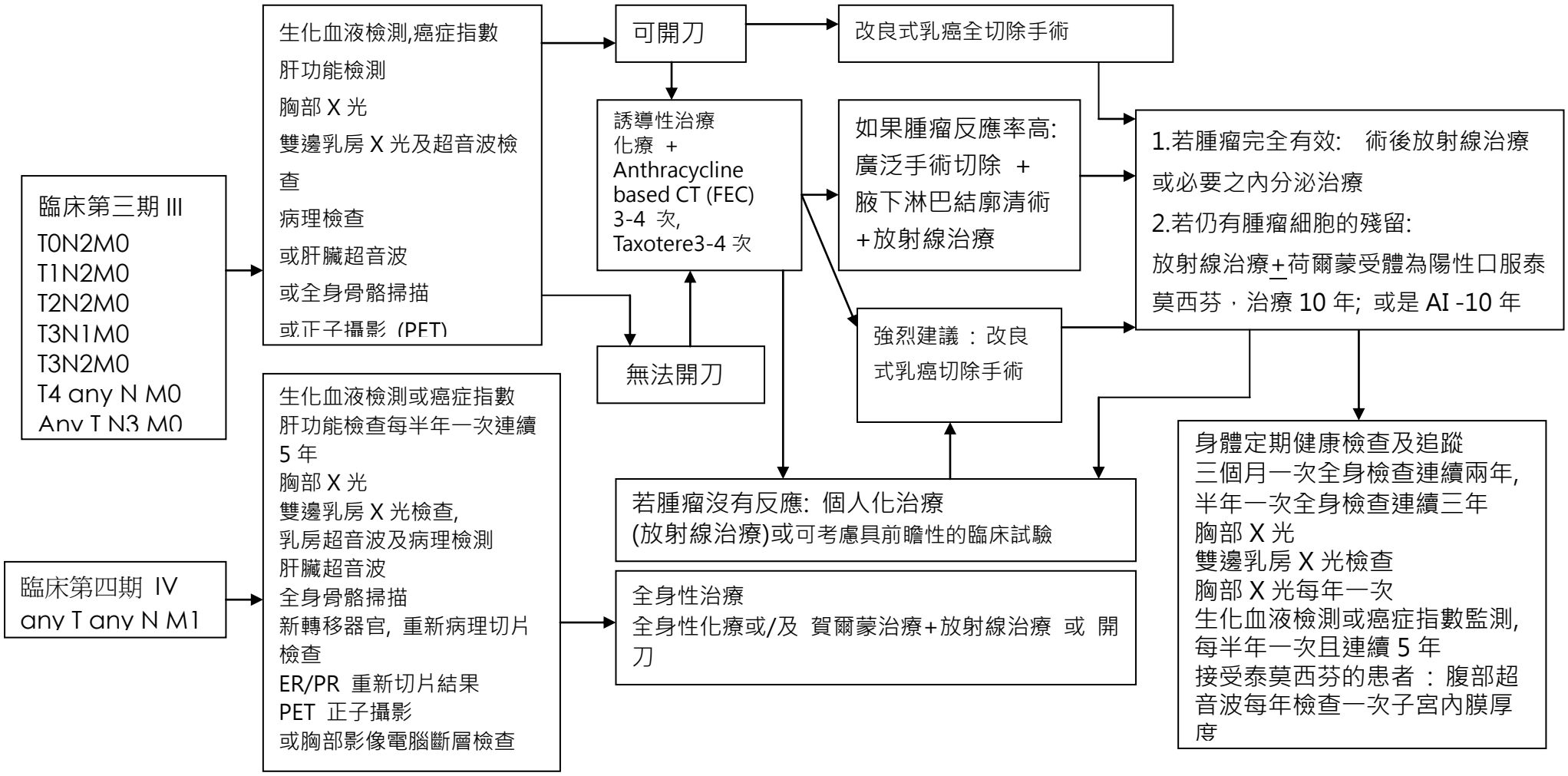
分化	1	2	3
大小	≦15mm	16-40mm	≧40mm
邊緣	≧10mm	1-9mm	<1mm
病理檢查定義	不是高度分化	Non-high	高度分化
	沒有壞死	有壞死	with or w/o
	G1,G2	G1,G2	G3
Age	>60	40-60	<40

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)
3. 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)

診 斷	檢 查	主 要 治 療	輔 助 治 療	追 蹤

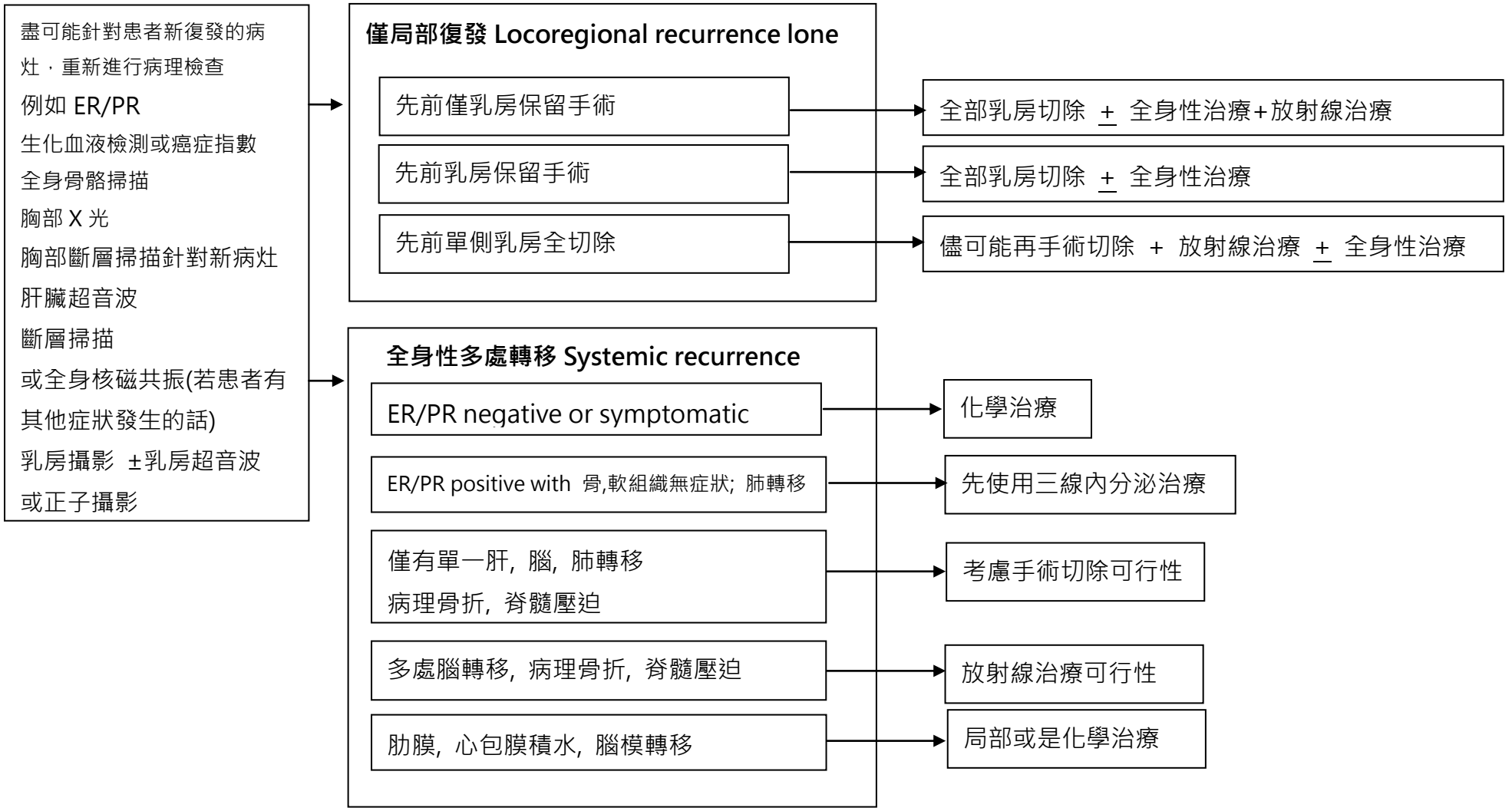


診斷	檢查	主要治療	輔助治療	追蹤



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 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 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



Treatment protocols from 2013-2016

Item/ Year	N0		N1 (LN 1-3)		N2 (LN 4-9)		N3 (LN >9)
	ER(+) or PR(+)	ER(-) & PR(-)	ER(+) or PR(+)	ER(-) & PR(-)	ER(+) or PR(+)	ER(-) & PR(-)	No matter ER/PR status
2013	FEC×6 or TC×4	FEC×3 and Taxotere×3	FEC×3 and Taxotere×3 (PACS01)	FEC×3 and Taxotere×3 (PACS01)	FEC×3 and Taxotere×3	FEC×3 and Taxotere×3	FEC×3 and Taxotere ×3
2014	FEC×6 or TC×4	FEC×3 and Taxotere×3	FEC×3 and Taxotere×3 (PACS01)	FEC×3 and Taxotere×3 (PACS01)	FEC×3 and Taxotere×3	FEC×3 and Taxotere×3	FEC×3 and Taxotere ×3
2015	FEC×6 or TC×4	FEC×3 and Taxotere×3	FEC×3 and Taxotere×3 (PACS01)	FEC×3 and Taxotere×3 (PACS01)	FEC×3 and Taxotere×3	FEC×3 and Taxotere×3	FEC×3 and Taxotere ×3
2016	FEC×6 or TC×4	FEC×3 and Taxotere×3	FEC×3 and Taxotere×3 (PACS01)	FEC×3 and Taxotere×3 (PACS01)	FEC×3 and Taxotere×3	FEC×3 and Taxotere×3	FEC×3 and Taxotere ×3

診斷	診斷檢察		
1. 乳葉原位癌切片確認 Stage 0 Tis, N0, M0	→	1. 病情詢問 2. 乳房攝影 3. 乳房超音波 4. 病理確認	→ 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

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

乳腺管內癌手術切除之邊緣考慮, 與臨床醫師及病理醫師科討論

1. 超過 10mm→不再做進一步手術
2. 1-10mm→與臨床醫師討論,是否加做後續治療？
3. <1mm→考量是否再做擴大切除

2015/12/21 增訂

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. 病理確認, ER, PR, Her2/neu, MIB-1 6. 腹部超音波 7. 骨骼掃描 (第 2B, 3A 期) 8. 腦部核磁共振 9. 正子檢查(第 3 期)	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

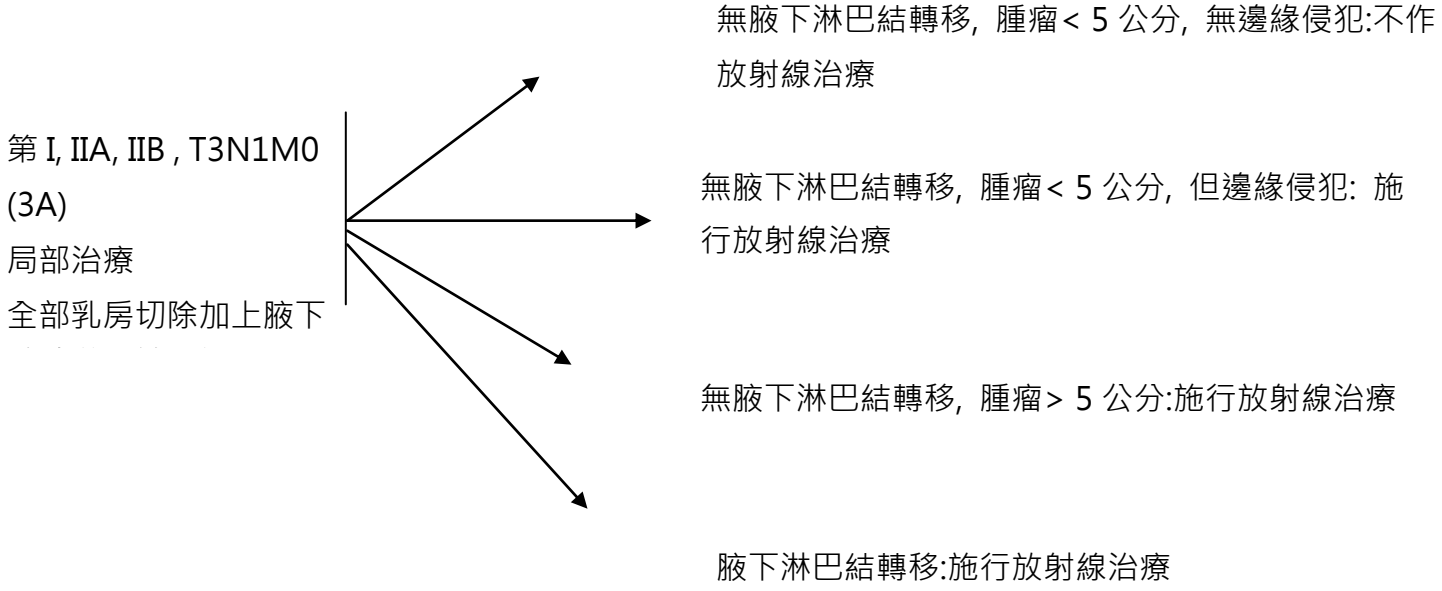
→ 無腋下淋巴結轉移, 術後放射線治療: 全部乳房

→ 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

(2015/12/21 增訂)

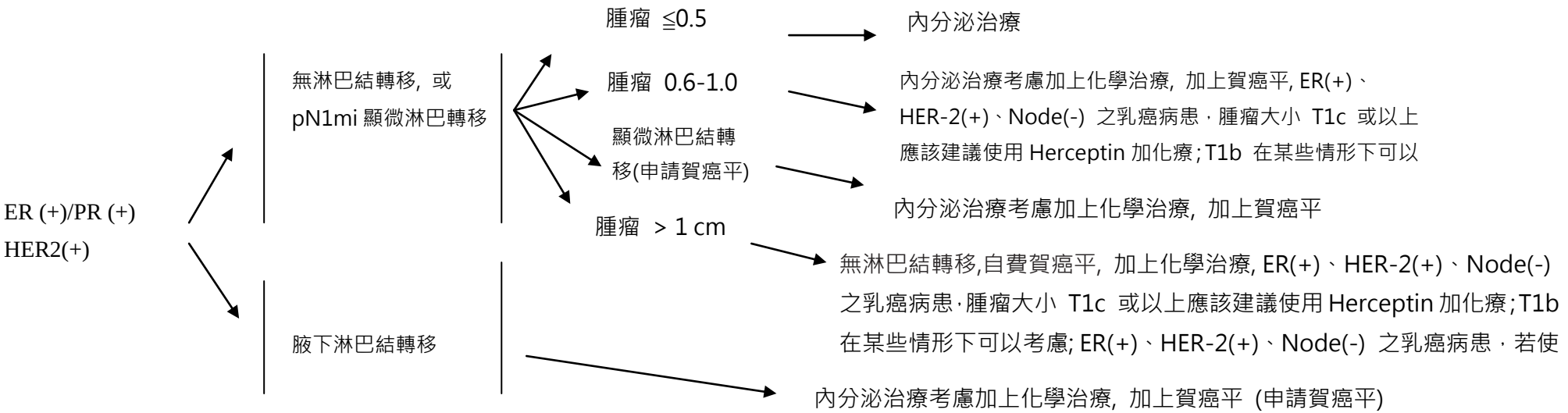
早期乳癌(第 1 期&第 2 期)如觸診, 未摸到腋下淋巴結應執行前哨淋巴切片，前哨淋巴切片結果如(-)，不應進行淋巴擴清。(2016/6/4 台灣乳房醫學會乳癌治療共識結果)

第 I, IIA, IIIB , T3N1M0 (3A) 局部治療



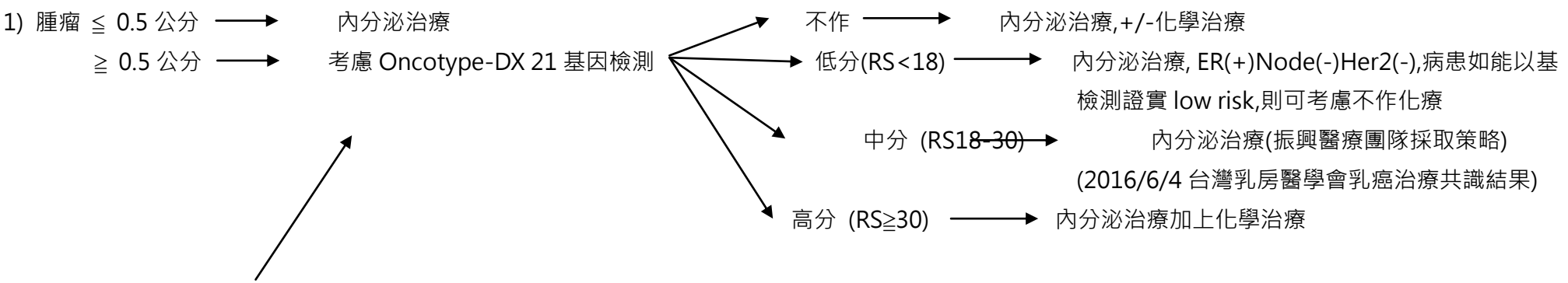
早期乳癌(第 1 期&第 2 期)如觸診, 未摸到腋下淋巴結應執行前哨淋巴切片，前哨淋巴切片結果如(-)，不應進行淋巴擴清。(2016/6/4 台灣乳房醫學會乳癌治療共識結果)

荷爾蒙接受器陽性,Her2/neu 陽性



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



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 台灣乳房醫學會乳癌治療共識結果)

Her2/neu 陽性

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

> 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 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)

＊ 淋巴結有轉移均考慮使用賀癌平加上化學治療

三陰性乳癌 (ER- , PR-, Her2/neu -)

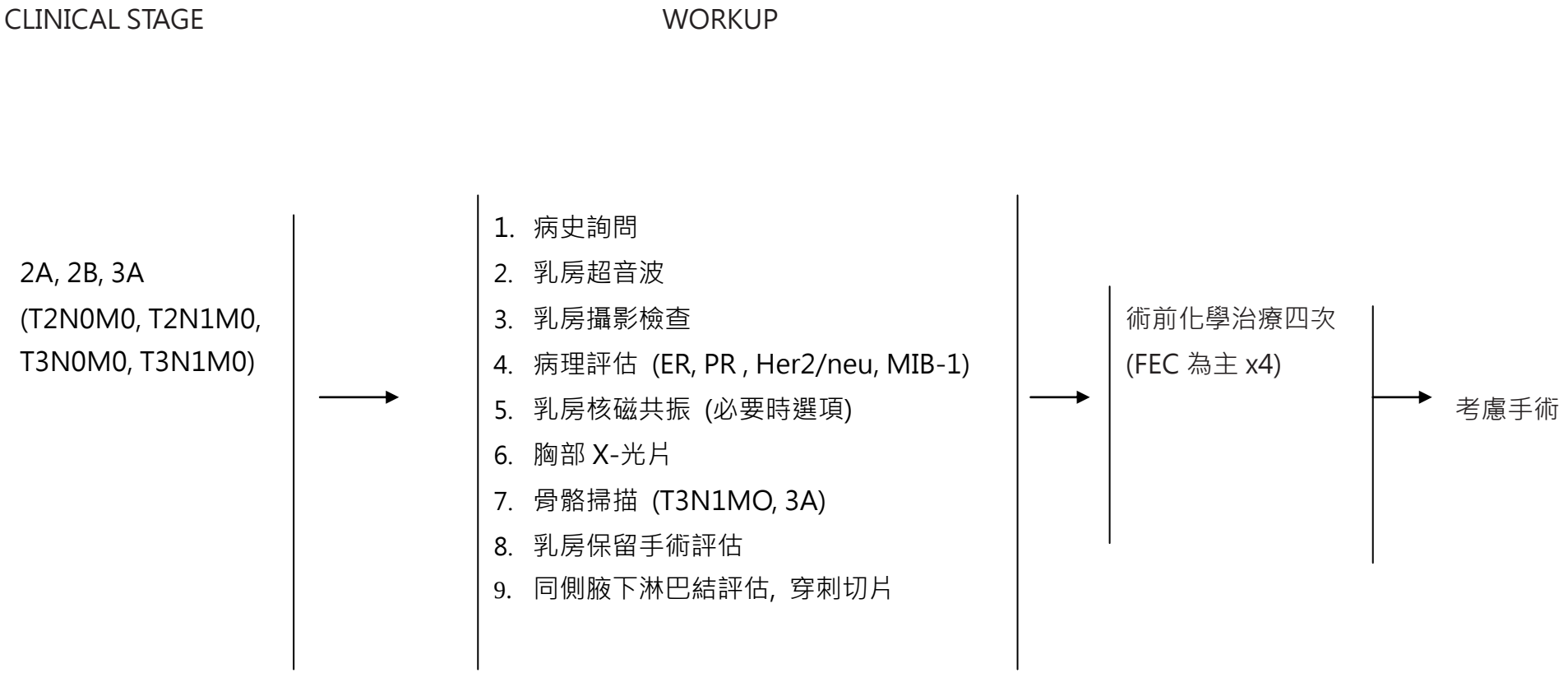
腫瘤≦0.5 公分 → 不作化學治療

>0.5 公分 → 化學治療 FECx3, 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)



＊ 年紀大, 心臟功能不佳, 考慮 Taxotaxel + Carboplain

NON-TRASTUZUMAB CONTAINING COMBINATIONS

NEOADJUVANT REGIMENS

TC

- Docetaxel (75)mg/m^2 IV day 1 (2016/01/25修訂)
- Cyclophosphamide 600 mg/m^2 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/m^2 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 (2016/04/29 修訂)

- Cyclophosphamide 600 mg/m^2 IV days 1
- Methotrexate 40 mg/m^2 IV days 1
- 5-Fluorouracil 600 mg/m^2 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.

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

- 5-Fluorouracil 500 mg/m^2 IV day 1
- Epirubicin 100 mg/m^2 IV day 1
- Cyclophosphamide 500 mg/m^2 day

Cycled every 21 days for 3 cycles.

Followed by

- Docetaxel **(** 75 **)** mg/m^2 day 1 (2016/01/25修訂)

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.

FEC (六次, 每 21 天一療程)

- 5-fluorouracil 500 mg/m^2 IV day 1
- Epirubicin 100 mg/m^2 IV day 1
- Cyclophosphamide 500 mg/m^2 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. Nnode(-)、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/m^2 IV day 1 (2016/01/25修訂)
- 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/m^2 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.

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

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. FEC 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/m^2 IV day 1

- ❖ Epirubicin 100 mg/m^2 IV day 1
- ❖ Cyclophosphamide 500 mg/m^2 day

Cycled every 21 days for 3 cycles.
Followed by

- Docetaxel (75) mg/m^2 day 1
- Cisplatin 60 mg/m^2 IVD day

Cycled every 21 days for 3 cycles. (2016/01/25修訂)

術後化療

NON-TRASTUZUMAB CONTAINING COMBINATIONS

ADJUVANT REGIMENS

TC (每三周一療程, 共四次)

- Docetaxel(75) mg/m^2 IV day 1 (2016/01/25修訂)
- Cyclophosphamide 600 mg/m^2 IV day 1

TC中的的“C”亦可使用Cisplatin 60 mg/m^2 IVD day 1

註:須評估年紀大,心臟功能 (2015/12/02修訂) **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.

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

- 5-Fluorouracil 500 mg/m^2 IV day 1
- Epirubicin 100 mg/m^2 IV day 1
- Cyclophosphamide 500 mg/m^2 day

  Followed by

  - Docetaxel **(75)** mg/m^2 day 1 (2016/01/25修訂)

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.

NON-TRASTUZUMAB CONTAINING COMBINATIONS

ADJUVANT REGIMENS

FEC (共六次, 每 21 天一療程)

- 5-fluorouracil 500 mg/m^2 IV day 1
- Epirubicin 100 mg/m^2 IV day 1
- Cyclophosphamide 500 mg/m^2 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.

1) TCH (共六次, 每 21 天一療程)

- Docetaxel (75) mg/m^2 IV day 1 (2016/01/25修訂)
- 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/m^2 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.

2) TRASTUZUMAB CONTAINING COMBINATIONS

OTHER ADJUVANT REGIMENS:

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

- Doxorubicin 60 mg/m^2 IV day 1
- Cyclophosphamide 600 mg/m^2 day 1
- Docetaxel (75)mg/m^2 (2016/01/25修訂)

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.

3) **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/m^2 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

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)

(1)手術後大於等於 11 年且無復發者不得使用。

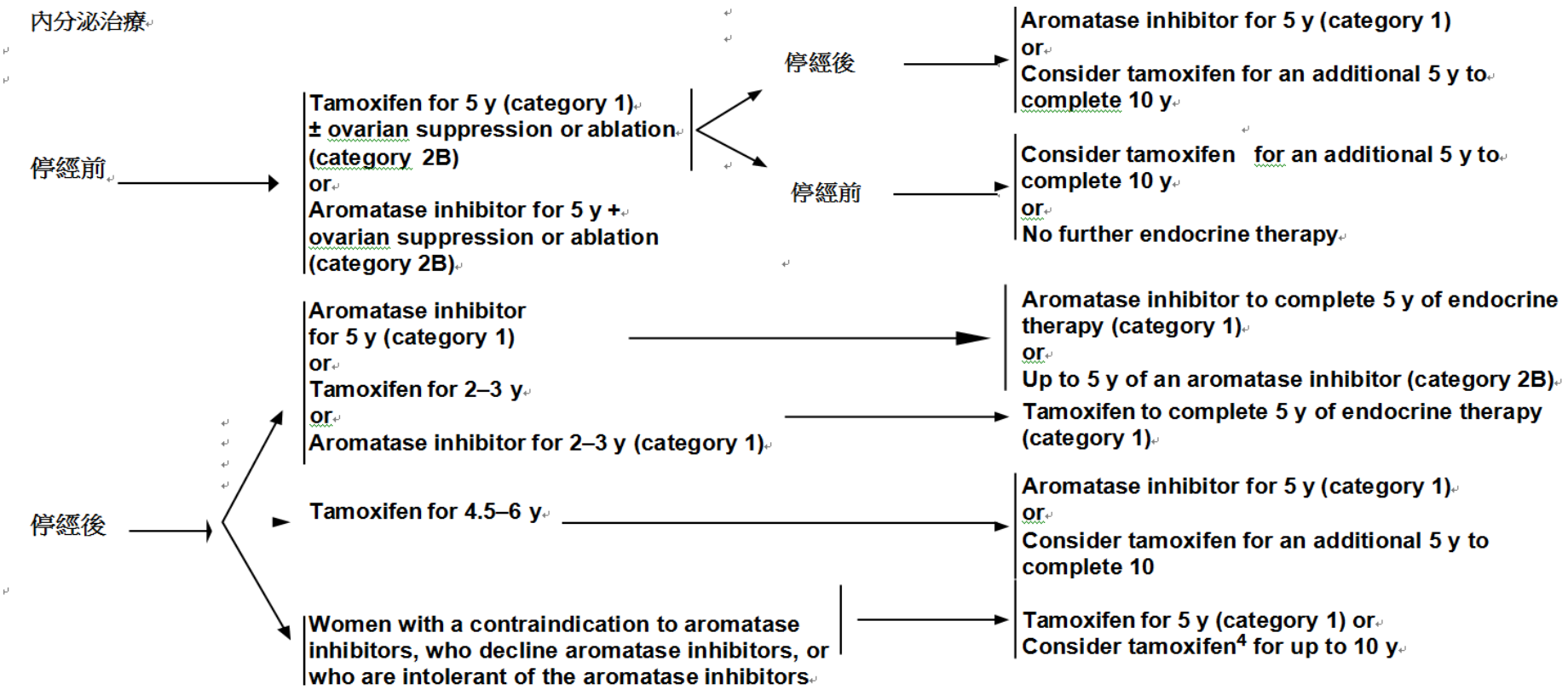
(2)每日最大劑量 2.5mg，使用不得超過四年。

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)

(1)每日最大劑量 2.5mg，使用不得超過五年；

(2)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. 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

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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一、放射治療政

Dose: 45-50Gy dose in 1.8-2.0 Gy fractions whole breast or chest wall / Reginal lymphatic

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Table 1

American Joint Committee on Cancer (AJCC)
TNM Staging System For Breast Cancer

Primary Tumor (T) The T classification of the primary tumor is the same regardless of whether it is based on clinical or pathologic criteria, or both. Size should be measured to the nearest millimeter. If the tumor size is slightly less than or greater than a cutoff for a given T classification, it is recommended that the size be rounded to the millimeter reading that is closest to the cutoff. For example, a reported size of 1.1 mm is reported as 1 mm, or a size of 2.01 cm is reported as 2.0 cm. Designation should be made with the subscript "c" or "p" modifier to indicate whether the T classification was determined by clinical (physical examination or radiologic) or pathologic measurements, respectively. In general, pathologic determination should take precedence over clinical determination of T size.

TX	Primary tumor cannot be assessed
T0	No evidence of primary tumor
Tis	Carcinoma in situ
Tis (DCIS)	Ductal carcinoma in situ
Tis (LCIS)	Lobular carcinoma in situ
Tis (Paget's)	Paget's disease of the nipple NOT associated with invasive carcinoma and/or carcinoma in situ (DCIS and/or LCIS) in the underlying breast parenchyma. Carcinomas in the breast parenchyma associated with Paget's disease are categorized based on the size and characteristics of the parenchymal disease, although the presence of Paget's disease should still be noted
T1	Tumor ≤20 mm or less in greatest dimension
T1mi	Tumor ≤1 mm in greatest dimension
T1a	Tumor >1 mm but ≤5 mm in greatest dimension
T1b	Tumor >5 mm but ≤10 mm in greatest dimension
T1c	Tumor >10 mm but ≤20 mm in greatest dimension
T2	Tumor >20 mm but ≤50 mm in greatest dimension
T3	Tumor >50 mm in greatest dimension
T4	Tumor of any size with direct extension to the chest wall and/or to the skin (ulceration or skin nodules).

Note: Invasion of the dermis alone does not qualify as T4

T4a	Extension to the chest wall, not including only pectoralis muscle adherence/invasion
T4b	Ulceration and/or ipsilateral satellite nodules and/or edema (including peau d'orange) of the skin, which do not meet the criteria for inflammatory carcinoma
T4c	Both T4a and T4b
T4d	Inflammatory carcinoma

Table 1 (continued)

Regional Lymph Nodes (N)

Clinical

NX		Regional lymph nodes cannot be assessed (e.g., previously removed)
N0		No regional lymph node metastasis
N1		Metastases to movable ipsilateral level I, II axillary lymph node(s)
N2		Metastases in ipsilateral level I, II axillary lymph nodes that are clinically fixed or matted; or in clinically detected* ipsilateral internal mammary nodes in the *absence* of clinically evident axillary lymph node metastases
	N2a	Metastases in ipsilateral level I, II axillary lymph nodes fixed to one another (matted) or to other structures
	N2b	Metastases only in clinically detected* ipsilateral internal mammary nodes and in the *absence* of clinically evident level I, II axillary lymph node metastases
N3		Metastases in ipsilateral infraclavicular (level III axillary) lymph node(s) with or without level I, II axillary lymph node involvement; or in clinically detected* ipsilateral internal mammary lymph node(s) with clinically evident level I, II axillary lymph node metastases; or metastases in ipsilateral supraclavicular lymph node(s) with or without axillary or internal mammary lymph node involvement
	N3a	Metastasis in ipsilateral infraclavicular lymph node(s)
	N3b	Metastasis in ipsilateral internal mammary lymph node(s) and axillary lymph node(s)
	N3c	Metastasis in ipsilateral supraclavicular lymph node(s)

**Note: Clinically detected* is defined as detected by imaging studies (excluding lymphoscintigraphy) or by clinical examination and having characteristics highly suspicious for malignancy or a presumed pathologic macrometastasis based on fine needle aspiration.

Pathologic (pN)*

pNX	Regional lymph nodes cannot be assessed (e.g., previously removed, or not removed for pathologic study)
pN0	No regional lymph node metastasis histologically

Note: Isolated tumor cell clusters (ITC) are defined as small clusters of cells not greater than 0.2 mm, or single tumor cells, or a cluster of fewer than 200 cells in a single histologic cross-section. ITCs may be detected by routine histology or by immunohistochemical (IHC) methods. Nodes containing only ITCs are excluded from the total positive node count for purposes of N classification but should be included in the total number of nodes evaluated.

pN0(i-)	No regional lymph node metastasis histologically, negative IHC
pN0(I+)	Malignant cells in regional lymph node(s) no greater than 0.2 mm (detected by H&E or IHC including ITC)
pN0(mol-)	No regional lymph node metastases histologically, negative molecular findings (RT-PCR)
pN0(mol+)	Positive molecular findings (RT-PCR),** but no regional lymph node metastases detected by histology or IHC

* Classification is based on axillary lymph node dissection with or without sentinel lymph node biopsy. Classification based solely on sentinel lymph node biopsy without subsequent axillary lymph node dissection is designated (sn) for "sentinel node," for example, pN0(sn).

** RT-PCR: reverse transcriptase/polymerase chain reaction.

Table 1 (continued)

Pathologic (pN) *(continued)*

pN1	Micrometastases; or metastases in 1–3 axillary lymph nodes; and/or in internal mammary nodes with metastases detected by sentinel lymph node biopsy but not clinically detected***
pN1mi	Micrometastases (greater than 0.2 mm and/or more than 200 cells, but none greater than 2.0 mm)
pN1a	Metastases in 1–3 axillary lymph nodes, at least one metastasis greater than 2.0 mm
pN1b	Metastases in internal mammary nodes with micrometastases or macrometastases detected by sentinel lymph node biopsy but not clinically detected***
pN1c	Metastases in 1–3 axillary lymph nodes and in internal mammary lymph nodes with micrometastases or macrometastases detected by sentinel lymph node biopsy but not clinically detected
pN2	Metastases in 4–9 axillary lymph nodes; or in clinically detected**** internal mammary lymph nodes in the *absence* of axillary lymph node metastases
pN2a	Metastases in 4–9 axillary lymph nodes (at least one tumor deposit greater than 2.0 mm)
pN2b	Metastases in clinically detected**** internal mammary lymph nodes in the *absence* of axillary lymph node metastases
pN3	Metastases in ten or more axillary lymph nodes; or in infraclavicular (level III axillary) lymph nodes; or in clinically detected**** ipsilateral internal mammary lymph nodes in the *presence* of one or more positive level I, II axillary lymph nodes; or in more than three axillary lymph nodes and in internal mammary lymph nodes with micrometastases or macrometastases detected by sentinel lymph node biopsy but not clinically detected*** ; or in ipsilateral supraclavicular lymph nodes
pN3a	Metastases in ten or more axillary lymph nodes (at least one tumor deposit greater than 2.0 mm); or metastases to the infraclavicular (level III axillary lymph) nodes
pN3b	Metastases in clinically detected**** ipsilateral internal mammary lymph nodes in the *presence* of one or more positive axillary lymph nodes; or in more than three axillary lymph nodes and in internal mammary lymph nodes with micrometastases or macrometastases detected by sentinel lymph node biopsy but not clinically detected***
pN3c	Metastasis in ipsilateral supraclavicular lymph nodes

*** "Not clinically detected" is defined as not detected by imaging studies (excluding lymphoscintigraphy) or not detected by clinical examination.

**** "Clinically detected" is defined as detected by imaging studies (excluding lymphoscintigraphy) or by clinical examination and having characteristics highly suspicious for malignancy or a presumed pathologic macrometastasis based on fine needle aspiration biopsy with cytologic examination.

Distant Metastasis (M)

M0	No clinical or radiographic evidence of distant metastases
cM0(I+)	No clinical or radiographic evidence of distant metastases, but deposits of molecularly or microscopically detected tumor cells in circulating blood, bone marrow, or other nonregional nodal tissue that are no larger than 0.2 mm in a patient without symptoms or signs of metastases
M1	Distant detectable metastases as determined by classic clinical and radiographic means and/or histologically proven larger than 0.2 mm

Table 1 (continued)

ANATOMIC STAGE/PROGNOSTIC GROUPS

Stage 0	Tis	N0	M0	**Stage IIIA**	T0	N2	M0
Stage IA	T1*	N0	M0		T1*	N2	M0
Stage IB	T0	N1mi	M0		T2	N2	M0
	T1*	N1mi	M0		T3	N1	M0
Stage IIA	T0	N1**	M0		T3	N2	M0
	T1*	N1**	M0	**Stage IIIB**	T4	N0	M0
	T2	N0	M0		T4	N1	M0
Stage IIB	T2	N1	M0		T4	N2	M0
	T3	N0	M0	**Stage IIIC**	Any T	N3	M0
				Stage IV	Any T	Any N	M1

* T1 includes T1mi

** T0 and T1 tumors with nodal micrometastases only are excluded from Stage IIA and are classified Stage IB.

- M0 includes M0(i+).
- The designation pM0 is not valid; any M0 should be clinical.
- If a patient presents with M1 prior to neoadjuvant systemic therapy, the stage is considered Stage IV and remains Stage IV regardless of response to neoadjuvant therapy.
- Stage designation may be changed if postsurgical imaging studies reveal the presence of distant metastases, provided that the studies are carried out within 4 months of diagnosis in the absence of disease progression and provided that the patient has not received neoadjuvant therapy.
- Postneoadjuvant therapy is designated with "yc" or "yp" prefix. Of note, no stage group is assigned if there is a complete pathologic response (CR) to neoadjuvant therapy, for example, ypT0ypN0cM0.

HISTOLOGIC GRADE (G)

All invasive breast carcinomas should be graded. The Nottingham combined histologic grade (Elston-Ellis modification of Scarff–Bloom–Richardson grading system) is recommended.[1,2] The grade for a tumor is determined by assessing morphologic features (tubule formation, nuclear pleomorphism, and mitotic count), assigning a value of 1 (favorable) to 3 (unfavorable) for each feature, and adding together the scores for all three categories. A combined score of 3–5 points is designated as grade 1; a combined score of 6–7 points is grade 2; a combined score of 8–9 points is grade 3.

HISTOLOGIC GRADE (NOTTINGHAM COMBINED HISTOLOGIC GRADE IS RECOMMENDED)

GX	Grade cannot be assessed
G1	Low combined histologic grade (favorable)
G2	Intermediate combined histologic grade (moderately favorable)
G3	High combined histologic grade (unfavorable)

HISTOPATHOLOGIC TYPE

The histopathologic types are the following:

In situ Carcinomas

NOS (not otherwise specified)
Intraductal
Paget's disease and intraductal

Invasive Carcinomas

NOS
Ductal
Inflammatory
Medullary, NOS
Medullary with lymphoid stroma
Mucinous
Papillary (predominantly micropapillary pattern)
Tubular
Lobular
Paget's disease and infiltrating
Undifferentiated
Squamous cell
Adenoid cystic
Secretory
Cribriform

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