2018
Early Breast Cancer
Neoadjuvant Consensus

台灣乳房醫學會 主編

台灣乳房醫學會
Breast Cancer Society of Taiwan

序

近年來，對於早期乳癌術前輔助治療(Neoadjuvant Systemic Therapy,NST)之初步評估、治療及後續追蹤等，皆須仰賴各領域專家之協調。為了推動台灣早期乳癌術前輔助治療(Neoadjuvant Systemic Therapy,NST)之交流，建立跨科別團隊照護共識，故而於西元2017年11月12日(星期日)由台灣乳房醫學會、台灣病理學會、臺北榮民總醫院共同主辦，假臺北榮民總醫院致德樓舉辦『2017 Neoadjuvant Leading Opinion Symposium』(詳如附件)，邀請國內放射影像、放射腫瘤、病理檢驗、乳房外科、腫瘤內科及個案管理師等專家學者們共同討論研究。

並於會後彙整專家共同建議，且經由台灣乳房醫學會第七屆理監事會議通過，並特別感謝以下專家-于承平醫師、王甄醫師、朱娟秀醫師、李玉嬋教授、杜世興醫師、沈士哲醫師、沈陳石銘理事長、林季宏醫師、侯明鋒醫師、俞志誠醫師、馬旭醫師、張金堅醫師、張振祥醫師、張潤忠醫師、張源清醫師、張献崑醫師、許志怡醫師、連晃駿醫師、連珮如乳癌個管師、郭文宏醫師、郭耀隆醫師、陳守棟醫師、陳芳銘醫師、陳訓徹醫師、陳詩華醫師、陳達人醫師、曾令民秘書長、黃俊升醫師、葉顯堂醫師、趙大中醫師、趙祖怡醫師、劉峻宇醫師、劉建良醫師、劉美瑾醫師、鄭翠芬醫師、鄭鴻鈞醫師、蕭正英醫師、賴瓊如醫師、戴明燊醫師、謝家明醫師、饒坤銘醫師(依姓氏筆劃排序)提供寶貴意見，彙編完成本手冊，以提供臨床醫療照護之參考依循。鑑往知來，醫學與時俱進，在許多專家學者們的持續努力之下，共同促進醫學之進步發展，亦誠摯期待各界先進能不吝指教、提供新知，達成全人醫療照顧之理念。

理事長　沈陳石銘

秘書長　曾 令 民

2018年7月

本治療共識謹做為參考，因每人狀況不同，而由各醫師選擇最適當之處置方式，不作為醫療訴訟用

附件

2017 Neoadjuvant Leading Opinion Symposium

Topic	Speaker	Moderator
Opening	台北榮總外科部 馬旭 部長 乳房醫學會 沈陳石銘 理事長	
乳癌新診斷個案病情告知技巧	國立台北護理健康大學 李玉嬋 教授	台北醫學大學附設醫院 杜世興 副院長
術前輔助治療個案管理經驗分享	台北榮總乳醫中心 連珮如 乳癌個管師	台北榮總乳醫中心 趙大中 醫師
Evaluation of treatment response to neoadjuvant systemic therapy of breast cancer by different imaging modalities	台中慈濟醫院影像醫學部心臟及胸腔影像科 陳詩華 主任	新光醫院一般外科 鄭翠芬 主任
Pre-treatment pathological evaluation	台大醫院病理部 連晃駿 醫師	台北醫學大學附設醫院病理科 朱娟秀 主任
Indication/patient selection and surrogate markers for NST	馬偕醫院乳房外科 張源清 醫師	三軍總醫院 俞志誠 教授
Recommendation for evaluation of axillary lymph node before and after neoadjuvant therapy	台大醫院外科部 郭文宏 醫師	台安醫院乳房外科 張金堅 總顧問
Recommendation of neoadjuvant systemic treatment regimens	台大醫院腫瘤醫學部 林季宏 醫師	台南新樓醫院乳房外科 張振祥 主任
Recommendation for management of primary tumor after neoadjuvant therapy	台北長庚一般外科 沈士哲 醫師	台灣乳房腫瘤手術暨重建醫學會 陳訓徹 理事長
Breast reconstruction after neoadjuvant chemotherapy	成大醫院斗六分院 郭耀隆 副院長	彰化基督教醫院全方位乳房腫瘤中心 陳達人 教授
Post-treatment pathological evaluation	台北榮總病理檢驗部 許志怡 主任	台灣病理學會 賴瓊如 理事長
Radiation therapy after post-neoadjuvant surgery for breast cancer	和信醫院放射腫瘤科 鄭鴻鈞 主任	和信醫院血液腫瘤科 劉美瑾 主任
Panel discussion	員林基督教醫院 陳守棟 協同院長 羅東博愛醫院 葉顯堂 醫療副院長 大同醫院癌症中心 陳芳銘 主任 三軍總醫院腫瘤科 戴明燊 主任 三軍總醫院病理科 于承平 主任 高雄長庚醫院血液腫瘤科 饒坤銘 醫師 台北榮總腫瘤醫學部 蕭正英 醫師 台北榮總放射線部 王甄 醫師	高雄小港醫院 侯明鋒 院長 台北榮總乳醫中心 曾令民 主任

Contents

* NST-Neoadjuvant Systemic Therapy

Evaluation of treatment response to neoadjuvant therapy of breast cancer by different imaging modalities

	Mammon/ To mo	US	MRI+C	Chest +Abdomen CT	Tc-99m bone scan whole body	FDG-PET/CT whole body
Initial Evaluation (Pre-Tx)	++++	++++	++	+++(±)		
After initiation or completion (Post-Tx)	++	+++	++			
Axillary evaluation (Pre-Tx)		++++	++			+
Axillary evaluation (Post-Tx)		++++	++			
Known breast cancer with clinical suspicion of metastatic disease				++++	++++	++++(±)

＋：**Strength of Recommendations**

1. “+” Specific standards?

Suggestion:

The increase in the number of “+” sign only represents the strength of the suggestion, not necessarily to be enforced, and should be applied according to depend on the circumstances of the case. This table is intended to provide recommendations and a quick checklist of the images type for clinical neoadjuvant therapy assessment.

2. If the Mammography, US or MRI measurements of tumor size vary widely, which measurement should be taken as a standard??

Suggestion:

Compare to mammography and US, the correlation between tumor size and pathologic findings measured on MRI images is the highest and strongest. But given the accessibility, repeatability and current treatment guidelines, ultrasound is still the top choice for follow-up therapy.

There are two reasons:

1) Ultrasound has no radiation and can be repeatedly used throughout the course of treatment, which is ideal for monitoring of the treatment continually.

2) The waiting list for ultrasound is relatively short, which avoids delays in the treatment.

* MRI – Magnetic Resonance Imaging

3. Is CT needed at the advanced stage?

Suggestion:

According to the literature, about 70% of advanced stage cases have been found metastasized at the initial diagnosis. As a result, CT is recommended.

As for the arrangements for FDG- PET / CT or CT, please attend to the current treatment guidelines of each center.

4. Axillary LN evaluation (Pre-Tx) Can also include CT?

Suggestion:

General assessment of axillary lymph nodes should be based on ultrasound.

However, when there is suspicion of distant metastasis, CT is recommended. But, whether to include CT scan in each neoadjuvant therapy case at the first assessment, the physician must refer to current treatment guidelines of each center.

* PET - Positron Emission Tomography

* CT - Computed Tomography

Pre-treatment pathologic evaluation

Pre-analytic

- The pre-treatment biopsy specimen will be the only available tumor tissue for further study, such as multiple gene assay, if pathological complete response is achieved. Therefore, the biopsy should contain adequate amount of invasive carcinoma. Ideally, 4 strips of biopsy using 16 or larger gauge core needle to obtain invasive carcinoma at least 5mm in length is recommended.

- The specimen cold ischemic time should be less than 1 hour for both the core biopsy and surgical specimen. The surgical specimen should be put into plastic bags with adequate formalin to fully cover the specimen. It is suggested not to pack specimen into bottles to avoid deformity. A simple cut of the specimen to enhance formalin penetration is acceptable.

Analytic

Because the quality of antibodies will greatly influence the staining result, it is strongly recommended to use highly sensitive, highly specific and clinically validated antibodies. It is also recommended to use automatic staining system to avoid human error.

Post analytic

- The criteria of positivity for ER and PR staining is well-established.Basically, nuclear staining in more than 1% tumor cells is regarded as positive.
- The current criteria of HER2 FISH follow the ASCO/CAP 2013 recommendation. For equivocal result, it is recommended to perform reflex tests using the probe for HER2 and CEP17 or using the probe for HER2 and alternative probe.
- The cut-off criteria for Ki-67 staining are still inconclusive both domestically and nationally. The Breast Pathology Committee is planning to conduct a national survey on the first, second and third quartile of Ki-67 staining ratio among different hospitals regarding hormone-positive breast cancers. The Committee will also prepare Proficient Test to evaluate the staining and reading qualities of Ki-67 among different hospitals. Hopefully the consensus regarding the Ki-67 staining will be reached soon. Potential heterogeneity about marker expression is still a potential cause which will cause problems in treatment. Multiple biopsies should be performed on any suspicious lesions detected by radiology to rule out potential tumor heterogeneity.

* ER- Estrogen Receptor
* PR- Progesteron Receptor
* FISH- Fluorescence In Situ Hybridization

Indication/patient selection and surrogate markers for NST

- The patients who fit the criteria of adjuvant therapy is the candidate of neoadjuvant treatment.
- Neoadjuvant therapy is the preferred schedule for patients with HER2+ and TN high risk breast cancer (≧T2 and/or N+).
- Neoadjuvant endocrine therapy for luminal-like tumors:

  *want to optimizes the option for breast conserving therapy and cannot /will not receive chemotherapy.

  *short term neoadjuvant endocrine therapy as function test of sensitivity is an option . (IMPACT, ACOSOG Z1031 B (Alliance), WSG-ADAPT, Plan B, LORELEI, NEOPAL clinical trial)

Non-candidates for neoadjuvant systemic therapy

*Patients with extensive in situ disease when extent of invasive carcinoma is not well-defined.

*Patients with a poorly delineated extent of tumor.

*Patients whose tumors are not palpable or clinically assessable.

Recommendation for evaluation of axillary lymph node before and after neoadjuvant therapy

Neoadjuvant systemic therapy planned

- If ipsilateral axillary lymph node evaluation is clinically negative-SNB is preferably performed after neoadjuvant systemic therapy .
- SNB can also be performed prior to NST in clinically node negative patients if knowledge of the pre-treatment SN histology is critical to treatment decision-making(e.g., application of NHI –reimbursed Herceptin).
- If SNB post-NST detects axillary metastasis or if the sentinel nodes are not identifiable-ALND is performed.
- If ipsilateral axillary lymph node biopsy is positive, axilla maybe restaged after neoadjuvant systemic therapy:
  - Axillary lymph node dissection (ALND) should be performed if axilla is clinically positive.
  - If the axilla is clinically negative after neoadjuvant therapy, SLNB can be performed in selected cases (category 2B)＃; otherwise ALND should be performed.

- Marking of sampled axillary nodes with a tattoo or clip should be considered to permit verification that the biopsy-positive lymph node has been removed at the time of definitive surgery.
- Data from the SENTINA Trial do not support the use of repeat SNB after NST due to an unacceptably low sentinel node identification rate and an exceedingly high false negative rate if neoadjuvant SNB showed positive result.
- ＃Among patients shown to be node-positive prior to neoadjuvant systemic therapy, SLNB has a >10% false-negative rate when performed after neoadjuvant systemic therapy. This rate can be improved by marking biopsied lymph nodes to document their removal, using dual tracer, and by removing more than 2 sentinel nodes.

- Several clinical trials have evaluated the feasibility of SNB after NST in patients with T1-3, N1-3 disease at baseline. Currently, NCCN guidelines support use of the SNB procedure after NST among previously node-positive patients converted to clinically node-negative. Acceptable SN false negative rates may be obtained when dual tracers (i.e., blue dye and radioisotope) are used for SN mapping, a minimum of three SN are removed, and when specimen radiography of the SN confirms removal of the original biopsy-positive axillary node. Under such circumstances, SNB-negative patients may avoid ALND whereas SNB-positive patients should undergo ALND. (4-8)
- Identification of the originally biopsied node may be facilitated by wire-guided or ultrasound-guided dissection. There may be a role for emerging nodal localization techniques, e.g., tattoo ink-guided or radioactive seed localization. A specimen radiograph of the resected node(s) should be obtained of the resected node(s) to document removal of any radio-opaque marker placed within a biopsy-positive node. (9, 10)

Source：
1.NCCN clinical practice Guidelines in oncology (NCCN Guidelines) version 1. 2018
2.AGO Recommendations for the Diagnosis and Treatment of Patients with Early Breast Cancer: Update 2018

Recommendation of neoadjuvant systemic treatment regimens

- The regimens recommended in adjuvant setting can be considered in neoadjuvant setting.
- Similar to that in adjuvant setting(with duration at least 18 weeks, recommend complete all chemotherapy if tolerable and no evidence of progression),the determination of regimens should be balanced in anti-tumor activity and toxicity to avoid under-or over-treatment.
- To avoid over-treatment for HER2+ disease, patients who fit the main characteristics (not eligibility) of adjuvant trial of weekly -paclitaxel/ trastuzumab or docetaxel / cyclophosphamide/ trastuzumab (tumor≤2cm, LN-, HR+) may prefer surgery first followed by standard adjuvant treatment.
- To avoid under-treatment for HER2+ disease, patients should consider completion of standard adjuvant regimens even the patients achieved pathological complete response. For advanced disease, with lymph node involvement, neoadjuvant dual blockade plus chemotherapy is the preferred regimen.
- Generally, the sample size of neoadjuvant trials is small, so most of them could not provide sufficient statistical power to demonstrate the survival difference. This weakness resulted in several controversial issues. For controversial issues, we need to evaluate the evidence from both of adjuvant and neoadjuvant setting.
- For triple negative breast cancer, additional use of platinum to taxane before or after anthracycline-based chemotherapy could be an option (not mandatory) for locally advanced disease although the survival benefit of adding platinum has not been consistently shown.

Recommendation for management of primary tumor after neoadjuvant therapy

- It is recommended to place a clip or tattooing in the primary tumor after biopsy.
- Resection into new margin is the goal of neoadjuvant therapy. The resection extent should be limited to residual lesions with reasonable safety margin.If no detectable lesion remains, the resection extent may be limited to the tissue in the immediate vicinity of the biopsy site marker.
- It is recommended to remove all suspicious microcalcifications after neoadjuvant therapy.
- Obtaining an image (mammography and/or ultrasound) for resected specimen is recommended.
- Placing multiple clips around the resection cavity is helpful for future radiotherapy planning.
- For patients whose negative margin were achieved after breast conserving surgery, but having large amount of tumor or scatter lesions presented in proximity to the margin, the decision for re-excision should be individualized and discussed in a multidisciplinary setting to determine if wider margins are needed.

Breast reconstruction after neoadjuvant therapy

- Nipple-skin sparing mastectomy with breast reconstruction is oncologically safe to perform in the setting of neoadjuvant therapy.
- As a whole, neoadjuvant therapy does not increase risk of major complications.
- If it is determined that the patient needs reconstruction before treatment, the plastic surgeon should be consulted.
- Consider mastectomy if positive margin after repeated excision, or radiotherapy is not feasible, inflammatory breast cancer, multicentric lesions, cT4a-c breast cancer.

Post-Treatment pathologic evaluation

- Specimens should be well oriented. May have a cut at the lesion for mastectomy specimen fixed in formalin. If possible, use suture to label the location of the lesion.
- Re-evaluate ER, PR, HER2 and Ki-67 for post-treatment specimens.

* ER-Estrogen Receptor

* PR-Progesteron Receptor

Radiotherapy for breast cancer patients after neoadjuvant systemic therapy

- Factors related to LRR after NAC in operable breast cancer

  —Major risk: (1) ypN(+), (2) breast non-pCR

  —Intermediate risk: (1) age<40, (2) tumor size >5cm, (3) cN(+)

- Require PMRT or RNI (if BCS) after NST

  —Patients with locally advanced breast cancer

  —Patients with ypN1 require PMRT/RNI

- Do not require PMRT/RNI

  —Stage I-II patients with a pCR (ypT0/Tis, ypN0). Breast irradiation is still necessary after BCS

- Suggest to have PMRT or RNI (for patients having BCS)

  —For cN(fn+) patients, especially TNBC (supported by MA20), even pCR has achieved

- The suggestion of PMRT/RNI should be based on these intermediate risk factors, i.e. (1) age<40,(2)tumor size >5cm, (3) cN (+)

*pCR- Pathological Complete Response

*PMRT- Postmastectomy Radiation Therapy

*RNI- Regional Nodal Irradiation

*BCS- Breast- Conserving Surgery

NOTE

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