Editorial Commentary

Updated interpretation for early breast cancer in The Chinese Society of Clinical Oncology Breast Cancer (CSCO BC) guidelines

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Introduction

As of 2020, the prevalence of female breast cancer has displaced lung cancer as the most diagnosed cancer worldwide (1). In China, the burden of breast cancer is also increasing rapidly (2). With improved coverage in breast cancer screening, most newly diagnosed breast cancer patients are diagnosed in the early stages [stage I–III as determined by the American Joint Committee on Cancer (AJCC) 8th edition staging system (3)]. Therefore, optimization of early breast cancer therapies is becoming increasingly critical.

The Chinese Society of Clinical Oncology Breast Cancer (CSCO BC) guidelines were developed by a multidisciplinary expert panel and have been updated annually since 2017. The 2021 updates of the CSCO BC guidelines were released in April 2021. In this new version, the CSCO panel focuses on indications of neoadjuvant therapy and has made significant advances in the recommendations of human epidermal growth factor receptor 2 (HER2)-positive, triple-negative, and hormone receptor (HR)-positive early-stage breast cancer management to personalize treatment. Critical trials that have led to significant changes in therapeutic choices are particularly emphasized in this article.

Advancements in indications of neoadjuvant therapy

Traditionally, foreign breast cancer guidelines have recommended that clinicians routinely use clinical stage and patient preferences to guide decision-making regarding whether or not to offer neoadjuvant therapy, as shown in previous National Comprehensive Cancer Network (NCCN) guidelines (prior to the 2020 updates). In contrast, molecular subtypes were considered in the indications of neoadjuvant therapy in the first version of the CSCO BC guidelines from as early as 2017. According to this guideline, candidates for neoadjuvant treatment should meet one of the following criteria: (I) large tumor size (>5 cm); (II) positive axillary nodes; (III) HER2-positive; (IV) triple-negative; (V) large primary tumor relative to breast size in patients who desire breast conservation. The selection criteria were also emphasized in the subsequent CSCO guidelines.

In the 2021 updates, the NCCN and CSCO guidelines for the indications of neoadjuvant therapy are generally concordant in their recommendations, with some differences to the American Society of Clinical Oncology (ASCO) recommendations (4). In the 2021 ASCO guidelines, for both HER2-positive and triple-negative breast cancer, patients with T1a N0 and T1b N0 should not be routinely offered neoadjuvant therapy outside of a clinical trial, while T1c N0 HER2-positive or T1cN0 triple-negative breast cancer (TNBC) patients could be considered for neoadjuvant therapy. However, currently, there is insufficient evidence from clinical trials or clinical practice to support T >1 cm as a tumor size threshold for neoadjuvant treatment. Therefore, most CSCO BC panel

members agree that when HER2-positive or triple-negative is used as the criteria to select breast cancer patients for neoadjuvant therapy, the tumor should be larger than 2 cm, and further confirmation is required from strictly designed clinical trials. This recommendation is more specific and applicable for guiding breast cancer treatment domestically.

It is worth noting that neoadjuvant therapy serves to decrease the extent of surgical intervention, improve survival, and enhance quality of life. It offers an opportunity to shrink the tumor in order to avoid unnecessary mastectomy, as confirmed by a meta-analysis conducted by the Early Breast Cancer Trialists' Collaborative Group (EBCTCG) (5). In this study, patients allocated neoadjuvant therapy in early breast cancer had a 16% increase in the frequency of breast-conserving surgery compared with the adjuvant chemotherapy group, with no increase in breast cancer mortality [34.4% *vs.* 33.7%; risk ratio (RR), 1.06; 95% confidence interval (CI): 0.95–1.18; P=0.31] or death from any cause (40.9% *vs.* 41.2%; RR, 1.04 95% CI: 0.94–1.15; P=0.45) at the 15-year follow-up. Moreover, in recent decades, a trend towards improvements in pathological complete response (pCR) rates in the neoadjuvant setting has been observed in several high-quality clinical trials, including NOAH (6), TRYPHAENNA (7), ADAPT (8), etc. Higher pCR rates offer new ideas of downstaging localized treatment, including downstaging to allow breast-conserving surgery, de-escalating axillary surgery, decreasing the extent of radiotherapy, and omission of surgery in clinically low-risk HER2-positive breast cancer with high HER2 addiction (9).

Updates in neoadjuvant therapy for HER2-positive early breast cancer

The regimen of recommendations for neoadjuvant and adjuvant therapies remain separated in the 2021 CSCO BC guidelines for HER2-positive breast cancer. In the adjuvant setting, docetaxel, carboplatin, trastuzumab, and pertuzumab (TCbHP) and anthracycline and cyclophosphamide followed by paclitaxel, trastuzumab, and pertuzumab (AC-THP) are both in the level I recommendation with evidence category IA. However, in the neoadjuvant setting, TCbHP is still in the level I recommendation with evidence category IA, while AC-THP is in the level II recommendation with evidence category 2B.

In the NCCN guidelines, both neoadjuvant and adjuvant therapies share the same regimens. The 2020 NCCN guidelines provided both anthracycline-based and anthracycline-free regimens in the presence of single or dual HER2 blockade as the preferred preoperative/adjuvant therapy regimens for HER2-positive breast cancer. However, in the 2021 NCCN guidelines update, anthracycline-containing regimens were removed from "preferred regimens" to "useful in certain circumstances", indicating the trend towards de-escalating anthracyclines in both neoadjuvant and adjuvant settings. In contrast, the 2021 St. Gallen consensus recommends anthracycline-based regimens as neoadjuvant therapy for HER2-positive node-positive patients, which were preferred by 61.82% of the consensus panel (10).

Contrary to NCCN guidelines, the CSCO panel states that neoadjuvant and adjuvant regimens should be separated. The therapeutic objectives of neoadjuvant/adjuvant therapies differ. Adjuvant therapy is administered after the tumor is dissected, with the goal of prolonging disease-free survival (DFS) and overall survival (OS). Meanwhile, aside from aiming to improving event-free survival (EFS), neoadjuvant therapy is delivered preoperatively with the short-term objective of shrinking the tumor even to achieve pCR. Consequently, although clinicians can prescribe the same regimens in both neoadjuvant and adjuvant settings, the CSCO panel recommends that neoadjuvant regimens should be those from which patients can benefit more rapidly. Also, because neoadjuvant therapy provides useful *in vivo* information about the sensitivity and efficacy of different regimens, recommendations for adjuvant therapy should be guided based on prognostic information provided by neoadjuvant therapy.

Currently, the value of anthracyclines in the management of early HER2-positive breast cancer is uncertain, as evidenced by the controversies of the CSCO guidelines, NCCN guidelines, and St. Gallen consensus in their 2021 updates. In the final analysis of BCIRG 006 (11), 10-year DFS was 74.6% with doxorubicin and cyclophosphamide followed by docetaxel and trastuzumab (AC-TH) (P<0.0001) and 73.0% with TCH (docetaxel, carboplatin, and trastuzumab) (P=0.0011). Although anthracycline-based regimens achieved superiority compared to anthracycline-free regimens in the adjuvant setting, they may not achieve better outcomes in the neoadjuvant setting. To evaluate the neoadjuvant therapy outcomes, EFS is usually used as an endpoint, which takes into consideration not only DFS in the adjuvant period, but also pCR rates in the neoadjuvant period, and events such as disease progression, metastasis, or death.

Based on the results from the NEOSPHERE trial (12), dual HER2 blockade together with chemotherapy has become a new standard of neoadjuvant therapy for HER2-positive breast cancer. Subsequent studies have shown that dual HER2 blockade with an anthracycline is not critical. In the TRYPHAENA study (13), TCbHP achieved a pCR of 66%, which was higher regardless of HR status compared to anthracycline-based regimens. The TRAIN-2 study (14,15) showed that in stage II/III HER2-positive patients who received dual HER2 blockade, pCR rate did not differ significantly between the anthracycline arm and non-anthracycline arm (67% *vs.* 68%, P=0.95). There was also no difference in the EFS with the addition or subtraction of the anthracycline, irrespective of HR and nodal status. Additionally, adverse effects were more common in the anthracycline-containing arm, including febrile neutropenia and a sustained left ventricular ejection fraction decline of >10% from baseline. Therefore, for early HER2-positive breast cancer patients, omitting anthracyclines from neoadjuvant therapy may be a preferred approach with higher efficacy and fewer side effects in the presence of dual HER2 blockade. Based on the evidence listed above and consensus from Chinese experts, the 2021 CSCO panel lists TCbHP in the level I recommendation, while AC-THP is in the level II recommendation.

Updates in adjuvant therapy for HER2-positive early breast cancer

In the "Adjuvant Therapy after Neoadjuvant Therapy for HER2-Positive Breast Cancer" section, patients are stratified according to types of neoadjuvant therapy received and pCR or not, in order to determine their treatment options. In the 2020 CSCO BC guidelines, if pCR was not achieved for patients receiving neoadjuvant dual HER2 blockade, trastuzumab emtansine (T-DM1) was recommended as level I, while HP (trastuzumab plus pertuzumab) was recommended as level II. However, in the 2021 updates, both T-DM1 and HP regimens are listed with level I recommendation. In the explanatory notes, for patients receiving dual HER2 blockade as a neoadjuvant therapy, the CSCO panel added that given the premise that all cycles are completed, the HP regimen is preferred if there is significant tumor growth reduction (e.g., Miller-Payne grades 3–4), while T-DM1 is preferred if the tumor growth reduction is not apparent (e.g., Miller-Payne grades 1–2). However, in the 2021 NCCN guidelines, the first choice for HER-2 positive patients with ypT1-4 ("py" prefix indicates pathologic staging following neoadjuvant therapy), N0, or ypN ≥1 should be T-DM1 alone. If T-DM1 is discontinued for toxicity, then T ± P (trastuzumab with or without pertuzumab) is recommended to complete the 1-year of therapy. However, since T-DM1 has not been covered by health insurance in China, the CSCO panel prefers the HP regimen owing to its better accessibility. Compared to the NCCN guidelines, the 2021 CSCO BC guidelines are more patient-centered and better meet the needs of Chinese patients.

Updates in neoadjuvant therapy for triple-negative early breast cancer

In the 2021 CSCO BC guidelines updates, the "Neoadjuvant Therapy for HER2-Negative Breast Cancer" section is divided into the "Neoadjuvant Therapy for Triple-Negative Breast Cancer" section and the "Neoadjuvant Therapy for Hormone Receptor-Positive Breast Cancer" section, which is the same in the adjuvant setting. Compared to the 2021 NCCN guidelines where TNBC and HR-positive/HER2-negative breast cancer are not separated, and neoadjuvant therapy still shares regimens with adjuvant therapy in HER2-negative breast cancer, the 2021 CSCO BC guidelines are significantly more specific.

HER2-negative breast cancer is heterogeneous. Compared to HR-positive/HER2-negative breast cancer, TNBC tends to be more undifferentiated, easier to metastasize, grow more rapidly, more sensitive to chemotherapy, with almost no response to endocrine therapy. Additionally, some TNBC patients are sensitive to immunotherapy, while most HR-positive/HER2-negative breast cancer patients respond poorly to immunotherapy. Furthermore, the SWOG S0221 study (16) indicated that the OS benefits from 2wAC→2wP (doxorubicin-cyclophosphamide once every 2 weeks followed by paclitaxel once every 2 weeks) regimen appeared to be confined to TNBC patients (P=0.067), with no differences observed in HR-positive/HER2-negative tumors (P=0.90). This trial adds to the body of evidence that TNBC and HR-positive/HER2-negative breast cancer should be separated in providing therapeutic guidance. Classifying recommended therapies for those two subtypes allows the 2021 CSCO BC guidelines to guide clinical practice in a more detailed and individualized way, and will hopefully lead to better implementation of precise medicine.

In the "Neoadjuvant Therapy for TNBC" section, the CSCO panel added "participation of strictly-designed

clinical trials, e.g., trials of nab-paclitaxel in combination with programmed cell death protein 1/programmed cell death ligand 1 (PD-1/PD-L1) inhibitors" as level II recommendation in the 2021 updates. Although immunotherapy is not yet been approved for early-stage TNBC, recent studies evaluating the addition of immunotherapy to standard neoadjuvant chemotherapy have demonstrated effects on pCR.

In the KEYNOTE-522 study (17), the addition of pembrolizumab to neoadjuvant chemotherapy regimens improved pCR rates by 13.6% (64.8% *vs.* 51.2%; P<0.001) and EFS by 6.0% (91.3% *vs.* 85.3%; HR, 0.63, 95% CI: 0.43–0.93) after 15.5 months of median follow-up regardless of PD-L1 status. The pCR rates were 68.9% versus 54.9% in the PD-L1-positive cohort. In the IMpassion-031 study (18), pCR was documented in 57.6% of patients in the atezolizumab plus chemotherapy group, compared with 41.1% in the placebo plus chemotherapy group. Atezolizumab combined with nab-paclitaxel and anthracycline-based neoadjuvant chemotherapy significantly improved pCR rates with an acceptable safety profile for patients with early-stage TNBC. The NeoTRIP study (19) showed no significant improvement in pCR [43.5% with atezolizumab *vs.* 40.8% with chemotherapy alone; odds ratio (OR), 1.11; P=0.66]. However, in patients with PD-L1-positive disease, pCR appeared to be significantly higher, with an OR of 2.08 (95% CI: 1.64–2.65).

These promising results suggest an important role for immunotherapy in the treatment of early TNBC. However, given that the evidence for selecting appropriate candidates for immunotherapy is insufficient, the CSCO panel lists neoadjuvant immunotherapy combined with chemotherapy as a level II recommendation, but only in well-designed clinical trials. Since identifying those who truly require these aggressive regimens is critical to prevent overtreatment in early TNBC, the CSCO panel encourages further investigation in this field.

Updates in adjuvant therapy for triple-negative early breast cancer

In the 2021 CSCO BC guidelines, the panel stratified TNBC breast cancer into "T >2 cm or lymph node-positive" and "T ≤2 cm and lymph node-negative". Level II recommendations were updated to include low-dose capecitabine maintenance therapy for TNBC patients with positive lymph nodes and T >2 cm. This recommendation was made based on the SYSUCC-001 study (20), where low-dose capecitabine maintenance therapy for 1-year resulted in significantly improved 5-year DFS (82.8% *vs.* 73.0%; HR, 0.64; 95% CI: 0.42–0.95; P=0.03) and 5-year OS (85.5% *vs.* 81.3%; HR, 0.75; 95% CI: 0.47–1.19; P=0.22) compared with observations among early-stage TNBC women who received standard adjuvant treatment. This regimen was also well-tolerated, with no unexpected serious adverse events detected. This trial was conducted at 13 academic centers and clinical sites in China and was led by Chinese investigators, contributing considerably to the development of this guideline.

Updates in neoadjuvant therapy for hormone receptor-positive early breast cancer

In the 2021 CSCO BC guidelines, the CSCO panel added a recommendation table to better present neoadjuvant chemotherapy regimens for HR-positive breast cancer. Anthracycline-taxane-based regimens are still the standard of care. Both TAC (docetaxel, anthracycline, and cyclophosphamide) and AT (anthracycline plus taxane) regimens are listed in level I recommendation with evidence category IA and 2A, respectively. The AC-T (anthracycline plus cyclophosphamide followed by taxane) regimen is in the level II recommendation with evidence category 1B.

A recommendation table of neoadjuvant endocrine therapy regimens was also added for endocrine therapy-dependent HR-positive patients who acquire treatment preoperatively but are not suitable to receive chemotherapy or surgery temporarily, or are not urgent to receive surgery. For postmenopausal patients, the (aromatase inhibitor) AI regimen is listed in the level I recommendation, while the level II recommendations include both the AI plus cyclin-dependent kinases 4 and 6 (CDK4/6) inhibitor and fulvestrant regimens. For premenopausal patients, neoadjuvant endocrine therapy is not recommended in principle. The ovarian function suppression (OFS) plus AI regimen and OFS plus AI plus CDK4/6 inhibitor regimen are included in the level II recommendation. In recent years, there have been an increasingly high number of trials testing new drugs in combination with endocrine agents for HR-positive patients. However, some inherent key issues remain unaddressed. For example, the indications, optimal length of treatment, and criteria for response evaluation have yet to be established. Therefore, neoadjuvant endocrine treatment is not routinely used in clinical practice.

Updates in adjuvant therapy for hormone receptor-positive early breast cancer

Almost no updates have been made for adjuvant endocrine therapy since 2020 in the CSCO BC guidelines. For treatment recommendations, stratification based on drug accessibility and sensitivity is still emphasized in the 2021 CSCO BC guidelines. Additionally, the explanatory notes added that genetic testing, as a risk stratification tool, could be considered to avoid unnecessary chemotherapy. The Oncotype DX [based on the TAILORx study (21)] and MammaPrint [based on the MINDACT study (22)] assays are available on the market in China, providing opportunities to optimize adjuvant therapies for certain early HR-positive breast cancer patients.

Conclusions

The CSCO BC guidelines have made enormous progress since 2017, especially for early breast cancer. Results from numerous clinical trials continue to expand therapeutic options, thereby guiding clinical decision-making, with Chinese clinicians, researchers, and public health authorities playing essential roles. There remains a long way to go, but we will undoubtedly contribute to breast cancer research and promote the standardized treatment of breast cancer in China and other countries.

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Footnote

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