Clinical practice guidelines for neoadjuvant therapy in patients with early-stage breast cancer: Chinese Society of Breast Surgery practice guidelines 2022

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Neoadjuvant therapy can yield clinical benefits in early-stage breast cancer with indications. The indications, treatment regimens, and efficacy of neoadjuvant therapy have been investigated, which have contributed valuable clinical evidence.[1,2] The Chinese Society of Breast Surgery convened a panel of breast disease experts to review and discuss the literature on neoadjuvant therapy for breast cancer and evaluate relevant evidence by referring to the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) system. Taking into account China's specific circumstances, the society and participating experts developed the *Clinical Practice Guidelines for Neoadjuvant Therapy for Early-stage Breast Cancer (Version 2022)* to serve as a reference for breast surgeons in China.

Level of Evidence and Recommendation Strength

The grading system for the level of evidence was developed by referring to the GRADE system and the findings from clinical studies in China, as indicated in the guideline evaluation system [Supplementary Table 1, http://links.lww.com/CM9/B963]. The recommendation strength of these guidelines combines the GRADE system and the specific characteristics of clinical practice in China [Supplementary Tables 2 and 3, http://links.lww.com/CM9/B963].

Recommendations

Qualifications of the neoadjuvant therapy team

The expert panel recommends that a multidisciplinary team (MDT) fully participate in the development and adjustment of neoadjuvant therapy strategies.[3] An MDT team should include members from the imaging, pathology, breast surgery, oncology, gynecology, genetic counseling, psychology, and nursing departments.

Indications for neoadjuvant therapy

The expert panel concurs with the indications for neoadjuvant therapy for early-stage breast cancer patients recommended by the Chinese Society of Clinical Oncology (CSCO) guidelines for breast cancer diagnosis and treatment. They highly recommend the implementation of neoadjuvant therapy for patients with indications. The indications for neoadjuvant therapy (grade IA) include a large tumor size (>5 cm), axillary lymph node metastasis, human epidermal growth factor receptor-2 (HER2)-positive breast cancer, triple-negative breast cancer, and breast-conservation intentions, but a large tumor size and breast volume pose a challenge for conserving the breasts.[1]

Neoadjuvant treatment regimen

The expert panel recommends that the standard adjuvant therapy regimen for breast cancer should serve as a reference when formulating neoadjuvant therapy strategies (grade IA). During neoadjuvant therapy, the appropriate dosage and duration of treatment should be administered (grade IA). The use of immune checkpoint inhibitors platinum drugs, or poly ADP ribose polymerase (PARP) inhibitors should be individualized (grade IA).[4]

Neoadjuvant therapy evaluation

The expert panel recommends conducting thorough evaluations before administering neoadjuvant therapy

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in breast cancer patients. The functions of vital organs should be evaluated by imaging and hematological examinations (grade IA) before neoadjuvant therapy.

Oncology evaluations should be performed before neoadjuvant therapy. A staged evaluation should be conducted following the American Joint Committee on Cancer (AJCC) (version 8), and distant metastasis should be excluded by computed tomography (CT), magnetic resonance imaging (MRI), positron emission tomography (PET)-CT, or radionuclide scans (grade IA).[5] The expert panel recommends conducting a description of the breast tumor and/or axillary lymph node diameter before treatment using ultrasound, X-ray, and dynamic enhanced MRI (grade IA). Localization and marking of lesions should be conducted using tattoo/tumor description/metal clip implantation before treatment (grade IA). Localization and marking of positive axillary lymph nodes should be conducted with metal clip implantation before treatment (grade IA). The expert panel recommends evaluating the efficacy of neoadjuvant therapy every two cycles, using the same imaging method as the one used at baseline, following the Response Evaluation Criteria in Solid Tumors (RECIST) (1.1) (grade IA).

The expert panel strongly recommends performing core needle biopsy (CNB)/vacuum-assisted breast biopsy (VABB) to obtain a histopathological diagnosis of breast lesions/lymph nodes before neoadjuvant therapy (grade IA). Secondary CNB and pathological evaluation of lesions can be performed for efficacy evaluation (grade IIA). Pathological efficacy evaluations should be conducted using the Miller & Payne/residual tumor burden (RCB) grading system (grade IA).

Surgery after neoadjuvant therapy

The expert panel recommends conducting planned neoadjuvant therapy for ≥4 cycles (grade IA). The timing of surgery following neoadjuvant therapy should be individualized, taking into account efficacy, patient compliance, tumor staging, and molecular typing.[6] Surgery should be recommended following imaging evaluations of clinical complete response (cCR) to neoadjuvant therapy (grade IA). Furthermore, surgery must adhere to the principle of achieving R0 resection (grade IA).

Systemic treatment after neoadjuvant therapy

The expert panel recommends that optional systematic treatment following neoadjuvant therapy should be determined by tumor staging, treatment response, and molecular typing (grade IA).[7]

Conflicts of interest

None.

Statement

These guidelines serve as a reference for breast disease specialists in clinical practice. However, these guidelines should not be used as the foundation for medical evaluation, nor do they arbitrate in any medical disputes. The guidelines are not intended for patients or non-breast specialists. The Chinese Society of Breast Surgery bears no responsibility for any results resulting from the improper application of these guidelines but reserves the right to interpret and revise the guidelines.

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