Review Article

Key points of breast cancer management under public health emergencies

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Abstract: Since the end of February 2022, China has experienced a new wave of coronavirus disease 2019 (COVID-19) outbreaks caused by the Omicron variant. These outbreaks frequently occur at multiple sites, involving many provinces and cities. Prevention and control work is facing more challenges only after the Wuhan epidemic. As a general principle, the priority of treatment should be determined according to the biological features, clinical stages, and treatment stages of different breast cancer (BC) subtypes, and individualized diagnosis and treatment recommendations should be given. These patients belong to a high-priority population, for whom receiving treatment in a hospital is urgently required. In addition, treatment should also be prioritized for patients experiencing new tumor-related symptoms or serious adverse events. If the disease condition is stable, the frequency of follow-up re-examinations can be reduced according to the epidemic control situation. Online diagnosis and treatment are recommended to maintain doctor-patient communication. However, special attention should still be paid to treatment-associated safety issues, and safety monitoring measures should be adopted. For low-priority patients with stable disease, elective follow-up visits may be arranged after risk-benefit assessment based on the severity of the local COVID-19 epidemic and the risk of infection. Based on the above principle, we once again present our opinions on the top ten hot issues concerning the clinical diagnosis and treatment of BC during the COVID-19 epidemic in China.

Keywords: Breast cancer (BC); coronavirus disease 2019 (COVID-19); Omicron variant; cancer management

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Introduction

The ongoing coronavirus disease 2019 (COVID-19) pandemic, which began early in 2020, has had a huge impact on the lives and work of people worldwide, including the diagnosis and treatment of breast cancer (BC). Clinicians often lack relevant data and resources in the diagnosis and treatment of this malignancy. Thus, we organized an expert panel to discuss ten hot issues in BC diagnosis and treatment in China during the COVID-19 epidemic and proposed our recommendations, hoping to offer specific strategies and guidance to both clinicians and patients. We have also conducted many real-world studies to explore the impact of COVID-19 on BC diagnosis and treatment (1). Since the end of February 2022, China has experienced a new wave of COVID outbreaks caused by the more transmissible Omicron variant. These outbreaks frequently occur at multiple sites, involving many provinces and cities. Prevention and control work is facing more challenges only after the Wuhan epidemic. Adhering to its

"dynamic clearing" policy, the Chinese government has coordinated the deployment of national medical forces to participate in the prevention and control of COVID-19 outbreaks in multiple cities and regions, and the epidemic situation is stable and improving. Nevertheless, the epidemic control measures and the imbalanced distribution of medical resources have unavoidably impacted the medical care of tumor patients to varying degrees. In particular, the hyper-transmissibility of the Omicron variant has resulted in high requirements for community prevention and control efforts and personal protective measures.

Therefore, in view of the recent research hotspots and based on the recently released "Chinese Society of Clinical Oncology (CSCO) Breast Cancer Guidelines 2022", we once again discussed many hot issues related to BC diagnosis and treatment under the context of regular COVID-19 prevention and control in China by summarizing the latest medical evidence, real-world data, and expert experience, and proposed our recommendations (2).

As a general principle, the priority of treatment should be determined according to the biological features, clinical stages, and treatment stages of different BC subtypes, and individualized diagnosis and treatment recommendations should be given. For example, for patients whose disease is life-threatening and progresses rapidly, it is expected that their survival and quality of life can be significantly improved after timely interventions. Thus, these patients belong to a high-priority population, for whom receiving treatment in a hospital is urgently required. In addition, treatment should also be prioritized for patients experiencing new tumor-related symptoms or serious adverse events. The priority of treatment for patients undergoing oral chemotherapy, endocrine targeted therapy, and/or human epidermal growth factor receptor 2 (HER2)-targeted therapies is medium. If the disease condition is stable, the frequency of follow-up re-examinations can be reduced according to the epidemic control situation. Online diagnosis and treatment are recommended to maintain doctor-patient communication. However, special attention should still be paid to treatment-associated safety issues, and safety monitoring measures should be adopted. For low-priority patients with stable disease (e.g., patients who are receiving adjuvant endocrine therapy or regular follow-up), elective follow-up visits may be arranged after risk-benefit assessment based on the severity of the local COVID-19 epidemic and the risk of infection. Based on the above principle, we once again present our opinions on the top ten hot issues concerning the clinical diagnosis and treatment of BC during the COVID-19 epidemic in China.

Management of breast masses

Breast tumors with a Breast Imaging-Reporting and Data System (BI-RADS) grade of IV or lower in breast imaging studies (including ultrasound, mammography, and MRI) can be observed for 1–2 months before a re-examination visit. For patients with breast masses discovered and identified by themselves with tumor-related symptoms and signs, imaging evaluation at a nearby hospital location is recommended (3).

For grade IV or above masses requiring further tests to rule out malignancy after clinical evaluation, a punch biopsy of the mass at a nearby hospital is encouraged. If imaging studies reveal a possibility of axillary lymph node metastasis, lymph node biopsy should also be performed during the same visit to confirm the diagnosis.

If no cancer cells are found in the punch biopsy, the mass can be observed for 1–3 months before a re-examination visit is arranged, which may determine whether an excision of the lesion is required.

If cancer cells are found in the punch biopsy but the mass is less than 3 cm in diameter and there is no lymph node metastasis, radical resection can be scheduled if the patient's condition allows. Intraoperative sentinel lymph node dissection is recommended as axillary lymph node dissection is associated with more postoperative complications and longer hospital stay.

If cancer cells are found in the punch biopsy and the tumor is ≥3 cm in diameter or the axillary lymph nodes are positive, appropriate neoadjuvant therapy should be selected based on clinical stage, molecular type, and doctor-patient communication results. Elective surgery may be performed after 6–8 cycles of preoperative neoadjuvant therapy.

Preoperative neoadjuvant treatment

Dual HER2-targeted therapy with trastuzumab plus pertuzumab, which may be combined with taxane chemotherapy or with taxane plus platinum chemotherapy, is preferred as the preoperative neoadjuvant therapy for HER2-positive BC. Because no hormonal pretreatment is required and weekly therapy is possible, nanoparticle albumin-bound (nab)-paclitaxel can be the preferred taxane. For hormone receptor (HR)-positive BC, neoadjuvant endocrine therapy can also be considered in addition to neoadjuvant chemotherapy. Aromatase inhibitors (AIs) are preferred but may be used in combination with CDK4/6

inhibitors. Ovarian suppression drugs can be added in premenopausal women. For triple-negative BC (TNBC), weekly nab-paclitaxel plus weekly carboplatin can be applied as the chemotherapy protocol (4). The treatment response should be closely observed, and the medications should be adjusted in a timely manner according to the blood cell counts.

For patients undergoing neoadjuvant therapy, the treatment should be continued as planned, if possible. However, based on the specific condition of the patient and the local epidemic control policy, the treatment protocol may be adjusted with reference to the above opinions. Treatment regimens with low toxicity and good efficacy can be used. For example, patients with HER2-positive BC can be switched to nab-paclitaxel in combination with trastuzumab plus pertuzumab and those with HR-positive BC can be switched to endocrine therapy. Nevertheless, the tumor status and treatment response must be recorded as possible when changing the regimen.

For patients who have completed neoadjuvant therapy, surgery should be performed within 4 weeks after the completion of neoadjuvant therapy; however, under special circumstances, it is reasonable to delay surgery for 2–4 weeks in stable patients. For patients who have benefited from neoadjuvant therapy but cannot receive surgical resection as planned, postoperative adjuvant therapy may still be applied. In order to maintain the continuity of treatment, drug therapy may be considered first: for HR-positive BC, use endocrine therapy; for HER2-positive BC, stop chemotherapy and continue the previously effective targeted therapy; for TNBC, consider oral capecitabine. In short, for patients who are temporarily unable to undergo surgery, low-toxicity, effective, and easy-to-manage drugs can be applied first, and surgery should be performed when the patient's condition permits.

Surgical treatment

During the regular COVID-19 prevention and control, surgical operations can be appropriately postponed: for patients with a benign tumor, the mass can be observed for 1–2 months before re-examination, and then a decision on surgery is made; for patients with a suspected tumor, punch biopsy can be performed first; and for patients with a confirmed diagnosis of BC, neoadjuvant drug therapy is preferred.

If surgical conditions permit, priority should be given to patients with the following conditions: (I) reoperation is required due to bleeding/infection after a previous BC surgery or for positive margins after breast-conserving surgery; (II) surgical management is required for complications after breast reconstruction surgery; (III) scheduled neoadjuvant therapy has been completed or the neoadjuvant therapy is planned to be terminated due to disease progression; and (IV) surgery is required to remove resectable locally recurrent lesions. In addition, for patients with highly invasive tumor types and/or with locally advanced disease accompanied by bleeding/infection, a more individualized surgical plan can be developed based on multidisciplinary team (MDT) discussions.

For patients who need immediate surgery, standard R0 resection should be performed using currently available resources, during which the surgical procedure should be optimized and the operative time should be shortened. If the tumor is small and the axillary lymph nodes are clinically negative, local tumor resection plus sentinel lymph node biopsy can be performed, and total mastectomy and axillary lymph node dissection should be avoided. For those who are not suitable for breast conservation, total mastectomy can be performed, and immediate or delayed breast reconstruction can be performed based on local epidemic control measures.

Since the COVID-19 control polices differ among different areas, clinicians are encouraged to "mutually recognize the diagnostic results and maintain the continuity of treatment". Patients may be referred to qualified hospitals within their province or municipality to receive the surgery, or they may undergo surgery in a local hospital with low COVID-19 risk.

Postoperative adjuvant therapy

The indications for adjuvant chemotherapy should be strictly followed, and unnecessary intensive chemotherapy should be avoided. If the patient's condition permits, multigene testing is encouraged for HR-positive BC patients with 0–3 positive axillary lymph nodes. The need for chemotherapy is determined after assessing the recurrence risk. For patients who need chemotherapy, its pros and cons should be carefully weighed and a chemotherapy regimen with a low risk of granulocytopenia should be chosen. The chemotherapy dose should be strictly calculated and should never exceed the maximum recommended dose. The combination of docetaxel with doxorubicin and cyclophosphamide (the TAC regimen) is not recommended. Postoperative chemotherapy can

be delayed for 2–4 weeks. Prophylactic white blood cell (WBC)-raising measures should be strictly implemented, for which long-acting granulocyte colony-stimulating factor is recommended (5). In principle, anthracycline combined with cyclophosphamide (AC) can be considered first, and 4 cycles of AC will be adequate for low-risk patients. If the risk of recurrence is high, sequential anthracycline-cyclophosphamide and taxane (AC-T) is recommended. Attention must be paid to the adverse reactions, like neutropenia, in some patients (i.e., young, TNBC, or *BRCA*-mutated patients) when adding platinum drugs to taxanes. For high-risk HER2-positive BC patients, sequential AC-T followed by targeted therapy (AC-T + HP) is recommended. For low- and intermediate-risk patients, weekly taxane plus targeted therapy may be considered. For low-risk or elderly patients with cardiovascular diseases or other comorbidities, the adjuvant HER2-targeted therapy may be stopped after 6 months of treatment when appropriate. Although nab-paclitaxel is not routinely recommended for adjuvant therapy, it may be a safer option in patients who have developed severe agranulocytosis after prior taxane-based chemotherapy or those who are at high risk for underlying agranulocytosis.

After the completion of initial adjuvant chemotherapy, a reasonable follow-up intensive treatment should be selected according to the patient's risk of recurrence. Sequential olaparib therapy can be considered in patients with *BRCA*-mutated, HER2-negative BC (6). Capecitabine can be used sequentially after chemotherapy for TNBC without *BRCA* mutation (7). Adverse reactions must be closely monitored when an intensified therapy is applied, especially during the COVID-19 control period. Oral drugs may be appropriately reduced or suspended in a timely manner to avoid unnecessary treatment-seeking behavior or treatment-associated risks due to adverse reactions.

For patients with HR-positive BC, adjuvant endocrine therapy can be used after chemotherapy or directly applied in low-risk patients who do not need chemotherapy. An oral AI or tamoxifen is the treatment of choice. For high-risk patients, abemaciclib may be added to AIs (8); however, patient education and proactive adverse event (e.g., neutrophils and diarrhea) management are critical. A once-every-3-month long-acting agent may be used in high- and medium-risk premenopausal patients who need ovarian function suppression. If the injection of an ovarian suppressing drug is not possible due to epidemic control, the ovarian suppression treatment can be appropriately postponed and tamoxifen alone can be used first.

In principle, adjuvant radiotherapy should be completed within 6 months after surgery. However, a delay of 1–2 months may be considered during the COVID-19 control period because the patients cannot go to the hospital for radiotherapy, to avoid frequent visits to hospitals and communities, and/or because of worry about radiation-induced pneumonitis and decreased immunity after radiotherapy. Adjuvant endocrine therapy or targeted therapy may be applied first. Once radiotherapy becomes possible, adjuvant radiotherapy should be prioritized for patients with high-risk BC (e.g., young patients, inflammatory BC, large or lymph node-positive tumors, TNBC or HER2-positive BC, and positive margins after a breast-conserving surgery). The priority patient population also includes patients who had received radiotherapy but whose radiotherapy course was interrupted due to the implementation of COVID-19 control measures (9).

Patient management during postoperative adjuvant treatment

Adjuvant endocrine therapy is typically given for 5–10 years. During the epidemic control period, longer repeat prescriptions issued in the outpatient departments will increase treatment adherence at home. Online diagnosis and treatment models (e.g., internet hospitals) and online follow-up visits and prescriptions are also useful to maintain the continuity of treatment. In addition, internet health care can be used to manage adverse effects associated with endocrine therapy.

For patients who are undergoing adjuvant targeted therapy, if they are at high risk for COVID-19, a delay of 6–8 weeks has little impact on overall efficacy. After the therapy is resumed, a loading dose can be re-administered, or the intervals between subsequent doses can be adjusted appropriately to ensure the overall dose intensity for the 12 months of treatment. If dual-targeted drugs cannot be infused during an extended period of time, a temporary switch to oral tyrosine kinase inhibitors (TKIs) may be considered as appropriate.

For patients undergoing adjuvant chemotherapy, the treatment principles for adjuvant therapy can be referred to: the treatment should be reasonably adjusted in light of the patient's condition so as to minimize the impact of the epidemic on treatment and minimize the risk of infection due to decreased immunity after chemotherapy. For some HR-positive BC patients who are receiving chemotherapy, if adjuvant chemotherapy is interrupted due to epidemic

control policies and will not resume within a short period of time, endocrine therapy may be performed first after careful consideration.

Switching from regular re-examinations to elective re-examinations

For patients who have completed postoperative adjuvant therapy, there is no need to maintain the original requirement for re-examination every 3–4 months, and a delay of 1–2 months is acceptable. In particular, bone scans, bone mineral density test, and head MRI can be postponed. If the patient is undergoing neoadjuvant therapy or if the tumor is asymptomatic or is maintained in a remission status, the imaging and clinical evaluation can be delayed, although it is recommended that the patients keep in touch with their doctors.

For patients who are receiving endocrine therapy, it is recommended to issue longer repeat prescriptions so that they can continue the medication without rushing to the hospital for re-examinations. For patients who are receiving molecular targeted therapy, follow-up outpatient echocardiography and/or electrocardiogram (ECG) can be postponed if there is no clinical symptom or sign during the treatment. For patients undergoing chemotherapy, the adverse reactions should be closely observed at each treatment session, during which the dose should be adjusted in a timely and reasonable manner to ensure the safety of chemotherapy.

For patients who are receiving treatment for recurrence and metastasis, the examination items can be simplified and optimized according to symptoms and tumor load, focusing on the examination of target lesions or organs presenting obvious symptoms. Lung CT may be considered because it is not only a common examination for BC but also a key diagnosis and screening tool for COVID-19. For patients with negative baseline findings and stable symptoms, routine bone scan, MRI, or other examinations are not recommended.

Treatment of recurrent/metastatic HR-positive BC

For HR-positive BC patients experiencing recurrence/metastasis, both chemotherapy and endocrine therapy are reasonable options. In the era of endocrine therapy alone, a significantly higher proportion of patients used chemotherapy as their first-line treatment (10). However, with the approval of more targeted drugs such as CDK4/6 inhibitors and histone deacetylase (HDAC) inhibitors in China, the therapeutic efficacy of endocrine therapy has been further improved. Since oral endocrine therapy can reduce the flow of people and lower the risk for COVID-19 transmission, it is a preferred therapy in the context of regular COVID-19 prevention and control to ensure the continuity of treatment.

Selection of the endocrine therapy regimen should be based on disease state, previous treatments, and convenience of treatment. Combination regimens may be selected when appropriate. For patients living in areas with high-risk levels of COVID-19, endocrine therapy alone may be considered first; if it is well tolerated after 2–4 weeks, combination with a targeted drug can be applied. For patients in low-risk areas, targeted drugs can also be started at an appropriately lowered dose, which can be adjusted according to the treatment response and adverse reactions. CDK4/6 inhibitors are preferred for targeted therapy-based combination treatment. However, different CDK4/6 inhibitors differ in terms of administration method and adverse reaction profile. Thus, drugs should be selected according to the patient's own status. Abemaciclib, which has less bone marrow and lung toxicity, can be considered as the first choice. According to the 2022 CSCO BC guidelines, endocrine therapy in combination with chidamide or another CDK4/6 inhibitor may be considered in patients who have failed one line of CDK4/6 inhibitor treatment. For patients who have failed two or more lines of endocrine therapy, the treatment strategy should be changed in a timely manner, and a reasonable chemotherapy regimen should be selected.

For patients undergoing chemotherapy, reasonable adjustments can be made according to the epidemic control situation. Real-world data has shown that switching to endocrine therapy in patients who respond to chemotherapy results in better progression-free survival (PFS). Therefore, for HR-positive advanced BC patients who are receiving chemotherapy, endocrine therapy can be used instead if the chemotherapy cannot be continued due to epidemic prevention and control policies.

Treatment of recurrent/metastatic HER2-positive BC

For patients with HER2-positive recurrent/metastatic BC, the treatment regimen should be selected according to the previous use of trastuzumab. The combination of the dual anti-HER2 antibodies pertuzumab and trastuzumab

with taxane-based chemotherapy should be selected for trastuzumab-responsive patients. Nab-paclitaxel is the preferred taxane formulation. If the treatment is effective, the original treatment regimen should be continued if the patient's condition permits. For patients who have completed 4–6 cycles of combination therapy and shown therapeutic response, the chemotherapy can be discontinued and the use of dual anti-HER2 antibodies can be continued as maintenance therapy.

Pyrotinib combined with capecitabine is the preferred regimen after trastuzumab failure (11). For some HER2-positive BC patients in whom dual-targeted infusion cannot be continued, this dual oral treatment regimen can be used.

For patients with pyrotinib treatment failure, the 2022 CSCO BC guidelines recommend the use of antibody-drug conjugates (ADCs) (e.g., T-DM1 and T-Dxd), HP combined with other chemotherapy drugs, or another TKI. However, the epidemic situation and the patient's past medical history should also be considered. In medium- and high-risk areas, oral targeted drugs are preferred, which can be used alone or in combination with oral chemotherapy drugs (or in combination with endocrine therapy in HR-positive BC patients). Patients in low-risk areas can choose novel anti-HER2 ADCs to delay tumor progression.

Treatment of recurrent/metastatic TNBC

Chemotherapy has been the mainstay of treatment for TNBC. In high-risk areas implementing strict COVID-19 control measures, combination chemotherapy should be avoided in TNBC patients. Single-agent chemotherapy can be used, preferably on a weekly basis. Genetic testing (e.g., for mutations in the *BRCA* and *PD-L1* genes) should be completed as soon as possible to facilitate safety management and regimen adjustments. PD-1 inhibitors have been proven to be effective in treating TNBC, with mild toxicity. For taxane-responsive patients, the combination of nab-paclitaxel and PD-1 inhibitors can be considered. For patients who fail taxane therapy, oral chemotherapy drugs such as capecitabine, vinorelbine, etoposide, and VP-16 can be considered. When the toxicity is tolerable, combination chemotherapy can be considered. In patients who cannot continue to receive infusion chemotherapy due to COVID-19 control policies, switching to the above oral chemotherapy drugs may be feasible.

The purpose of palliative chemotherapy for advanced BC is to prolong survival and increase quality of life. Metronomic chemotherapy may be a useful strategy. For patients with a relatively small tumor load or poor immunity after multiple lines of treatment, the administration of chemotherapeutic drugs may be less frequent or even suspended for supportive care so as to maximize the quality of life and allow more home stay.

Patient management in special times

During the regular COVID-19 prevention and control, it is important to strengthen the whole-process management of BC patients. Patients in low-risk areas should adhere to standard treatment regimens. For patients in high-risk areas, however, the treatment plan should be adjusted reasonably according to local control measures. China currently implements a strict "dynamic clearing" policy; meanwhile, the quiet and rapid spread of the Omicron variant has resulted in scattered COVID-19 outbreaks in many provinces. The community-based control of COVID-19 is currently short-term, multi-center, and unpredictable. Some communities where BC patients live in implement COVID-19 control measures, and the duration uncertainty makes it difficult to decide whether the treatment strategy should be adjusted immediately. Therefore, during the epidemic control period, medical institutions and medical staff must be fully aware of the government's COVID-19 control information and the local epidemic control measures and scientifically develop diagnosis and treatment strategies for BC patients. The initial BC treatment protocol should follow principles including low toxicity, oral formulations, best efficacy, and long-term protection. In addition, modern communication technology as well as network service platforms [including CSCO BC artificial intelligence decision-making system (12), network hospitals, drug transportation cloud platforms, and patient case management system] are valuable to ensure patients receive standard treatment. Patients should also be instructed to keep abreast of the information released by the medical institution, pay attention to the epidemic control requirements in a timely manner, and make full use of the online outpatient clinic to maintain close communication with their doctors and obtain prescription drugs. Patients should be able to protect themselves from viral infection and manage their disease at home. Efforts should be made to minimize drug interruption and treatment suspension due to COVID-19 control measures and reduce other issues caused by dietary

and emotional problems.

Timely and reasonable vaccination is an effective way to prevent COVID-19. BC patients, especially those who are undergoing treatment, are a vulnerable population for COVID-19. The Chinese government encourages voluntary COVID-19 vaccinations and works to ensure all people eligible for vaccination have access to it, especially the homologous and heterologous COVID-19 booster vaccinations. Although there is no sufficient evidence on COVID-19 vaccination in special populations, patients with different subtypes of BC and in different clinical stages can be vaccinated in a timely and safe manner under the guidance of their doctors. Based on the currently available expert opinions and clinical data, the CSCO BC Committee has developed the first Chinese expert consensus on vaccinating BC patients against COVID-19 (13), which will also be updated in June this year. We encourage BC patients to receive COVID-19 vaccination reasonably and scientifically, so as to lower the real-time impact of the epidemic on BC diagnosis and treatment.

Conclusions

To sum up, in the context of regular COVID-19 prevention and control in China and guided by the spirit of "scientific decision-making and humanistic care", oncologists should actively participate in the fight against COVID-19 to minimize the impact of the epidemic on BC treatment. Proactive efforts should be made to protect tumor patients from viral infection and ensure continuity of treatment. BC patients should be guided to receive COVID-19 vaccination, so as to reduce the infection rate and the proportion of critical cases while taking into account the treatment of BC. Under the leadership of the Communist Party of China and the Chinese government and thanks to the hard work and dedication of medical staff, we have accumulated rich experience in the management of BC patients during this special period. Accordingly, we have developed a series of expert consensuses and principles to prioritize and adjust diagnosis and treatment protocols for BC patients when they face social emergencies. These documents are expected to offer useful experience and information to BC doctors, patients, and other stakeholders and ensure the safety and effectiveness of anti-tumor therapies when social emergencies occur or when patients encounter uncontrollable difficulties during the treatment period.

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Footnote

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://tbcr.amegroups.com/article/view/10.21037/tbcr-22-28/coif). ZJ serves as the Editor-in-Chief of *Translational Breast Cancer Research*. JL serves as an unpaid Managing Editor of *Translational Breast Cancer Research*. The other author has no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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