Clinical practice guidelines for ultrasound-guided breast lesions and lymph nodes biopsy: Chinese society of breast surgery (CSBrS) practice guidelines 2021

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With the maturation and advances of image-guided puncture biopsy technology, the proportion of open breast biopsy has gradually decreased. Ultrasound-guided biopsy is convenient in practice and supports real-time visualization. In order to standardize the practice of ultrasound-guided breast and regional lymph node biopsy, and provide a reference for Chinese breast surgeons, based on the version of Consensus statements and operation guidelines on breast lesions and lymph nodes biopsy guided by ultrasound (2019),[1] the Chinese Society of Breast Surgery (CSBrS) has re-evaluated the quality of the evidence of relevant clinical studies referring to the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) handbook and considered domestic medical condition to develop the Clinical Practice Guidelines for Ultrasound-guided Breast Lesions and Lymph Nodes Biopsy: CSBrS Practice Guidelines 2021.

Level of evidence and recommendation strength

Level of evidence standard[2]

Recommendation strength standard[2]

Recommendation Strength Review Committee

A total of 79 members of the voting committee of this guideline, including 68 breast surgeons (86.1%), two oncologists (2.5%), four radiologists (5.1%), two pathologist (2.5%), one radiation therapist (1.3%), and two epidemiologists (2.5%).

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Target Audience

Clinicians specializing in breast diseases in China.

Recommendations

Recommendation 1: Indications

	Site	Indications	Level of evidence	Recommendation strength
1.1	Breast Lesion	Breast Imaging Reporting and Data System (BI-RADS) category ≥ 4[3-5]	I	A
1.2		BI-RADS category 3 with a family history of breast cancer or other high-risk factors[1]	II	A
1.3		Possible for neoadjuvant therapy[3,4]	I	A
1.4		Benign lesion for further pathological classification[4]	I	A
1.5	Regional Lymph Node	Suggested by imaging with abnormal histomorphology and (or) structure, and suspected of being metastatic[6]	I	A

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Recommendation 2: Methods for breast lesion biopsy

	Methods for breast lesion biopsy	Level of evidence	Recommendation strength
2.1	Fine-needle aspiration biopsy (FNAB)[5]	III	B
2.2	Core needle biopsy (CNB)[3,7,8]	I	A
2.3	Vacuum-assisted breast biopsy (VABB)[4]	I	A

Recommendation 3: Methods for regional lymph node biopsy

	Methods for regional lymph node biopsy	Level of evidence	Recommendation strength
3.1	FNAB[9]	I	A
3.2	CNB[6]	I	A

Recommendation 4: Clinical issues on breast lesion biopsy

	Clinical issues on breast lesion biopsy	Level of evidence	Recommendation strength
4.1	Needle size for breast lesion CNB		
4.1.1	14G[10-12]	II	A
4.1.2	16G[10-12]	II	A
4.1.3	18G[10,12]	III	B
4.2	≥ 4 specimens for breast lesion CNB to improve the diagnostic rate (with 14G needle)[13,14]	II	A
4.3	CNB or VABB specimens may have pathological underestimation of the following breast lesions		
4.3.1	High-risk lesions: Papilloma[15,16]	I	A
4.3.2	Atypical ductal hyperplasia (ADH)[4,16]	I	A
4.3.3	Phyllodes tumor[16,17]	II	A
4.3.4	Radial sclerosing lesion[16]	II	A
4.3.5	Carcinoma *in situ*[4,16]	I	A

Discussion

The contraindications of ultrasound-guided breast lesion or regional lymph node biopsy can refer to the general principles for preoperative evaluation, including severe systemic diseases, mental disorders, inability to cooperate, and severe bleeding or coagulation disorder. The following conditions should be considered as relative contraindications and be treated carefully regarding the status of individuals: prosthesis-adjacent lesions and lesions with macro-calcification.

Yu *et al*[5] reported the satisfying sensitivity and specificity of fine-needle aspiration biopsy (FNAB) with adequate sample obtained for diagnosis, in a meta-analysis of 46 studies involving 7207 patients; however, in 11 studies which reported unsatisfactory samples, 27.5% of patients were subsequently upgraded to various grade cancers. The diagnosis and treatment of breast cancer have entered the era of molecular typing, while FNAB cannot provide histopathology. In addition, cellular immunohistochemistry has not been popularized and standardized domestically yet. Therefore, the expert panel does not recommend FNAB as a first-line method for breast lesion biopsy.

The core needle biopsy (CNB) can collect specimens for histopathological diagnosis. The diagnostic sensitivity of CNB is 96%,[3] and the findings on the status of estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor 2 (HER-2) expression in CNB specimens show good consistency with the immunohistochemical findings of surgical specimens.[7,8] There is no direct clinical evidence showing decreased overall survival of patients undergoing a CNB for breast cancer,[18] but we recommend resecting the needle track during the breast surgery to minimize the probability of cancer recurrence and metastasis. However, CNB specimens may show false-negative findings and histopathological underestimation for small lesions, heterogeneous tumors, or special pathological types.[19] Youk *et al*[16] systematically reviewed 2,420 lesions from 2,198 women who undergone sonographically guided 14-gauge CNB, and the results suggested that the underestimate rate was 29% for ductal carcinoma in situ (DCIS) and the overall underestimation rate of high-risk lesions was 27%, in which the underestimation rate of atypical ductal hyperplasia (ADH) and other high-risk lesions was 52% and 17% respectively. It is thereby seen that CNB has a relatively high pathological underestimation rate for the diagnosis of special pathological types. More details on vacuum-assisted breast biopsy (VABB) usage and diagnostic underestimation can be found in Clinical Practice Guidelines for Ultrasound-guided Vacuum-assisted Breast Biopsy: CSBrS Practice Guidelines 2021.[20] Clinicians should consider performing a subsequent open surgical resection to make a definitive diagnosis for the above-mentioned conditions. Open surgical biopsy should also be conducted if there is an obvious inconsistency between the puncture biopsy results and the imaging examination.

Ultrasound-guided FNAB was most frequently used in the clinic for regional lymph nodes biopsy; however, it only supports cytological materials collection. It cannot accurately identify abnormal morphology or the structure of lymph node tissues, or execute the immunohistochemical evaluation of the tumor, which may result in the pathological underestimation. CNB can well make up for the shortcomings of FNAB. Balasubramanian *et al*[6] found that the sensitivity of the diagnosis of a lymph node metastasis was 88% for ultrasound-guided CNB and 74% for FNAB in general. The specificity of CNB and FNAB were similar, approaching 100%. Since both the axillary and clavicular regional lymph nodes are usually adjacent to blood vessels and nerves, an ultrasound-guided biopsy should be carefully performed with the use of a suitable needle to minimize secondary injuries.

Conflicts of interest

The expert committee for these guidelines declares no conflict of interest.

These guidelines are a reference for breast disease specialists in clinical practice. However, the guidelines are not to be used as the basis for medical evaluation, and do not play an arbitrating role in the handling of any medical disputes. The guidelines are not a reference for patients or non-breast specialists. The Chinese Society of Breast Surgery assumes no responsibility for results involving the inappropriate application of these guidelines, and reserves the right to interpret and revise the guidelines.

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