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

Jin-Fei Ma¹, Lu-Yan Chen², Shuang-Ling Wu¹, Ying-Ying Xu¹, Fan Yao¹, Feng Jin¹, Pei-Fen Fu², Bo Chen¹, Chinese Society of Breast Surgery

¹Department of Breast Surgery, The First Affiliated Hospital of China Medical University, Shenyang, Liaoning 110001, China;²Department of Breast Surgery, The First Affiliated Hospital, Zhejiang University, School of Medicine, Hangzhou, Zhejiang 310003, China.

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 standard²

Recommendation strength standard³

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%).

Target Audience

Clinicians specializing in breast diseases in China.

Recommendations

Recommendation 1: Indications

| Site | Indications | Level of evidence | Recommendation strength |
|------|-------------|-------------------|-------------------------|
| 1.1  | Breast Imaging Reporting and Data System (BI-RADS) category ≥ 4⁴⁻⁵ | I | A |
| 1.2  | BI-RADS category 3 with a family history of breast cancer or other high-risk factors⁴⁻⁶ | II | A |
| 1.3  | Possible for neoadjuvant therapy⁵⁻⁶ | I | A |
| 1.4  | Benign lesion for further pathological classification⁶ | I | A |
| 1.5  | Regional lymph node suspected of being metastatic⁵⁻⁶ | I | A |

Jin-Fei Ma and Lu-Yan Chen contributed equally to this work.

Correspondence to: Dr. Pei-Fen Fu, Department of Breast Surgery, The First Affiliated Hospital, Zhejiang University, School of Medicine, Hangzhou, Zhejiang 310003, China
E-Mail: Peifen_Fu@163.com
Dr. Bo Chen, Department of Breast Surgery, The First Affiliated Hospital of China Medical University, Shenyang, Liaoning 110001, China
E-Mail: bochen@cmu.edu.cn

Copyright © 2021 The Chinese Medical Association, produced by Wolters Kluwer, Inc. under the CC-BY-NC-ND license. This is an open access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially without permission from the journal.

Chinese Medical Journal 2021;134(12)
Received: 05-02-2021 Edited by: Yan-Jie Yin and Xiu-Yuan Hao
Recommendation 2: Methods for breast lesion biopsy

| Methods for breast lesion biopsy | Level of evidence | Recommendation strength |
|---------------------------------|-------------------|-------------------------|
| 2.1 Fine-needle aspiration biopsy (FNAB) | III | B |
| 2.2 Core needle biopsy (CNB) | I | A |
| 2.3 Vacuum-assisted breast biopsy (VABB) | I | A |

Recommendation 3: Methods for regional lymph node biopsy

| Methods for regional lymph node biopsy | Level of evidence | Recommendation strength |
|---------------------------------------|-------------------|-------------------------|
| 3.1 FNAB | I | A |
| 3.2 CNB | 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 | II | A |
| 4.1.2 16G | II | A |
| 4.1.3 18G | III | B |
| 4.2 ≥ 4 specimens for breast lesion CNB to improve the diagnostic rate (with 14G needle) | II | A |
| 4.3 CNB or VABB specimens may have pathological underestimation of the following breast lesions |                  |                         |
| 4.3.1 High-risk lesions Papilloma | I | A |
| 4.3.2 Atypical ductal hyperplasia (ADH) | I | A |
| 4.3.3 Phyllodes tumor | II | A |
| 4.3.4 Radial sclerosing lesion | II | A |
| 4.3.5 Carcinoma in situ | 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 injecting the needle track during the breast surgery to minimize the probability of cancer recurrence and metastasis. However, CNB specimens may show false-negative 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 underwent sonographically guided 14-gauge CNB, and the results suggested that the underestimate rate was 29% for ductal carcinoma in situ (DCIS) and the overall underestimate rate of high-risk lesions was 27%, in which the underestimate 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.
Breast Surgery assumes no responsibility for results medical disputes. The guidelines are not a reference for breast disease: a meta-analysis. Br J Surg 2008;95:1017–1021. doi: 10.1007/s12282-015-0624-9.

10. Ohashi R, Matsubara M, Watarai Y, Yanagihara K, Yamashita K, Tsuchiya S, et al. Diagnostic value of fine-needle aspiration and core needle biopsy in diagnosing axillary lymph node metastasis. Brit J Surg 2018:105:1244–1253. doi: 10.1002/bjs.10920.

11. Asogan A, Hong G, Armi Prabhakaran S. Concordance between core needle biopsy and surgical specimen for oestrogen receptor, progesterone receptor and human epidermal growth factor receptor 2 status in breast cancer. Singapore Med J 2017;58:145–149. doi: 10.11622/smmed.2016062.

12. Motamedehshariati M, Memar B, Aliakbarian M, Shakeri M, Samadi M, Jangoo A. Accuracy of prognostic and predictive markers in core needle breast biopsies compared with excisional specimens. Breast Care (Basel) 2014;9:107–110. doi: 10.1159/000360787.

13. Verkooijen H, Peeters P, Buskens E, Koot V, Borel Rinkes I, Mali W, et al. Diagnostic accuracy of large-core needle biopsy for nonpalpable breast disease: a meta-analysis. Br J Cancer 2000;82:1017–1021. doi: 10.1038/sj.bjc.6600679.

14. Kirshenbaum K, Keppke A, Hou K, Dickerson M, Gajjar M, Kirshenbaum G. Reassessing specimen number and diagnostic yield of ultrasound guided breast core biopsy. Breast 2012;18:466–469. doi: 10.1016/j.breast.2012.01.026.

15. Chang J, Han W, Moon W, Cho N, Noh D, Park I, et al. Papillary lesions initially diagnosed at ultrasound-guided vacuum-assisted breast biopsy: rate of malignancy based on subsequent surgical excision. Ann Surg Oncol 2011;18:2506–2514. doi: 10.1245/s10434-011-1617-3.

16. Youk J, Kim E, Kim M, Oh K. Sonographically guided 14-gauge core needle biopsy of breast masses performed with 14-gauge, 16-gauge and 18-gauge automated cutting needle biopsy devices, and review of the literature. Eur Radiol 2012;27:2928–2933. doi: 10.1007/s00330-016-4651-5.

17. Fishman J, Milikowski C, Ramsinghani R, Velasquez M, Aviram G. US-guided core-needle biopsy of the breast: how many specimens are necessary? Radiology 2003;226:779–782. doi: 10.1148/radiol.226301162.

18. Liebens F, Carly B, Cusumano P, Van Beveren M, Beier B, Fastrez M, et al. Diagnostic value of vacuum-assisted breast biopsy: Chinese Society of Breast Surgery practice guidelines 2021. Chin Med J 2021;134:894. doi: 10.1097/CMD.0000000000001549.

19. How to cite this article: Ma JF, Chen LY, Wu SL, Xu YY, Yao F, Jin F, Fu PF, Chen B. Clinical practice guidelines for ultrasound-guided breast lesions and lymph nodes biopsy: Chinese society of breast surgery (CSBrS) practice guidelines 2021. Chin Med J 2021;134:1393–1395. doi: 10.1097/CMS.0000000000001508.