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Clinical practice guidelines for ultrasound-guided vacuum-assisted breast biopsy: Chinese Society of Breast Surgery (CSBrS) practice guidelines 2021

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Ultrasound-guided vacuum-assisted breast biopsy (VABB) is a common technique in breast surgery. To standardize this technique, the Chinese Society of Breast Surgery (CSBrS) re-evaluated the quality of evidence for clinical studies of VABB, referring to the grading of recommendations assessment, development, and evaluation, and developed the Clinical Practice Guidelines for Ultrasound-guided vacuum-assisted breast biopsy: CSBrS Practice Guidelines 2021, in accordance with the Expert Consensus and Operation Guidelines for Ultrasound-guided Vacuum-assisted Breast Biopsy Surgery (2017) combined with data from clinical practice in breast surgery in China, providing a reference for breast surgeons in China.

Level of evidence and recommendation strength

Level of evidence standard[1]

Recommendation strength standard[1]

Recommendation strength review committee

There were 82 voting committee members for this guideline: 66 from breast surgery departments (80.5%), six from medical oncology departments (7.3%), four from medical imaging departments (4.9%), two from pathology departments (2.4%), two from radiotherapy departments (2.4%), and two epidemiologists (2.4%).

Target Audience

Clinicians specializing in breast diseases in China.

Recommendations

Recommendation 1: Diagnostic indications.

Indications	Level of evidence	Recommendation strength
1.1 Ultrasound diagnosis of breast breast imaging reporting and data system (BI-RADS) classification ≥IV lesions[2,3]	I	A

Recommendation 2: Treatment indications.

Indications	Level of evidence	Recommendation strength
2.1 BI-RADS classification III lesions with surgical indications.[4,5]	I	A

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Recommendation 3: VABB contraindications.

Contraindications	Level of evidence	Recommendation strength
3.1 Bleeding tendency, blood coagulation disorder, and related disorders.[3,4,6]	I	A
3.2 Patients with serious systemic diseases who cannot tolerate surgery.[3,4,6]	I	A

Recommendation 4: Clinical problems.

Treatment of post-operative hematoma.

Principle	Level of evidence	Recommendation strength
4.1.1 Incision is necessary for hemostasis or debridement if a patient is suspected of having active bleeding, or has a huge hematoma causing severe pain.[7]	I	A

Principles for the treatment of high-risk lesions.

Principles	Level of evidence	Recommendation strength
4.2.1 When the lesion is confirmed to be completely removed and histopathologically confirmed to be atypical ductal hyperplasia, open surgery excision should be performed.[8]	II	A
4.2.2 When the lesion is confirmed to be completely removed and histopathologically confirmed to be benign phyllodes tumor, surveillance is justified.[8]	II	A
4.2.3 When the lesion is confirmed to be completely removed and histopathologically confirmed to be borderline or malignant phyllodes tumor, open surgery excision should be performed.[8]	II	A
4.2.4 When the lesion is confirmed to be completely removed and histopathologically confirmed to be classical lobular neoplasia, flat epithelial atypia, radial scars, or papillary lesions, surveillance is justified.[8]	II	A

Discussion

The expert group believes that ultrasound guided VABB is safe, fast, effective, economical, without radioactivity, and permits monitoring the location of the biopsy needle in real time.[4,6,9] The VABB technique was approved by the US Food and Drug Administration (FDA) in April 1995. In 1999, the American Medical Association announced that image-guided VABB is a reliable diagnostic technique that replaces surgical biopsy. In 1999, the technique was approved by the China Food and Drug Administration for clinical use in China. In 2004, the US FDA approved VABB for "total excision of abnormalities found in imaging," that is, the technique can be applied to remove benign breast lesions.[9] After VABB was introduced in China, because of the high cost, it was mainly used for treatment purposes and was extensively recognized by breast surgeons and patients. With the continuous upgrading of this technique, its applications are increasingly extensive, and it is currently used for diagnosis and treatment in breast surgery.

According to previous reports, VABB is superior to core needle biopsy (CNB) in terms of the specificity of the histopathological diagnosis of lesion biopsy for diagnosis. The underestimation rates of VABB and CNB for ductal carcinoma *in situ* in a previous study were 9% and 38%, respectively, and the underestimation rates of these techniques for high-risk lesions were 11% and 25%, respectively.[10] According to the recommendations of the expert group, the indication of VABB for diagnostic purposes is ultrasound diagnosis of breast imaging reporting and data system (BI-RADS) classification ≥IV lesions,[2] especially for lesions with small volumes (largest diameter <1.0 cm). VABB is also preferred for biopsy of lesions adjacent to the chest wall or a prosthesis.[5,10] For lesions with inconsistent results by imaging evaluation and CNB, VABB can be performed again to enhance the diagnostic accuracy.[2] For VABB used for diagnosis, the expert group recommends that a clip can be placed simultaneously to enhance the accuracy of lesion resection in subsequent open surgery, reduce the rate of secondary resection of the incision margins in breast-conserving surgery, and reduce recurrence. For patients receiving neoadjuvant treatment, positioning a clip can avoid difficulty in confirming the location of the original lesion after complete clinical remission, which can facilitate subsequent surgery.[6,11]

VABB for treatment is indicated for BI-RADS classification III lesions with surgical indications. For BI-RADS classification III lesions measuring ≤2.0 cm, the complete resection rate of VABB is nearly 100%, while for lesions measuring >2.0 cm, the probability of residual lesions is positively correlated with the tumor size.[2,5,8,12]

The expert group has not yet discussed VABB for treating gynecomastia, accessory breast, breast abscess, and early breast cancer because of the lack of evidence from prospective randomized controlled trials.

Hematoma is a common complication after VABB, and small-volume hematomas do not require treatment. The expert group considers that surgery is necessary for hemostasis or debridement if a patient is suspected of having active bleeding or has a huge hematoma causing severe pain.[7]

High-risk breast lesions are composed of a group of heterogeneous lesions (atypical ductal hyperplasia, lobular neoplasia, flat epithelial atypia, radial scars, papillary lesions, phyllodes tumors, and others). The highest risk of these lesions for malignancy is 35% after total resection.[8] The expert group believes that therapeutic open surgical excision should be performed for atypical ductal hyperplasia after VABB, and for some special cases, surveillance is justified after multidisciplinary discussion. For benign phyllodes tumors with complete resection confirmed by imaging, surveillance is justified. For borderline and malignant phyllodes tumors, open surgical excision should be performed to obtain negative margins. However, in the National Comprehensive Cancer Network guidelines, regardless of whether the phyllodes tumors are benign, borderline, or malignant, negative margins must be ≥1.0 cm; therefore, treatment for phyllodes tumors should be chosen cautiously. When the lesion is confirmed to be completely resected by imaging and is pathologically confirmed as classic lobular neoplasia, flat epithelial atypia, radial scars, or a papillary lesion, surveillance is justified. When the pathological diagnosis is highly inconsistent with the clinical diagnosis, multidisciplinary consultation is required.

Appendix: Opinion views on ultrasound-guided VABB

(Supplementary file, http://links.lww.com/CM9/A553).

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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