

Clinical practice guideline for breast fibroadenoma: Chinese Society of Breast Surgery (CSBrS) practice guideline 2021

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Breast fibroadenoma is the most common benign tumor of the breast in women, and can occur at all ages. However, these tumors are more commonly seen in women aged 15 to 35 years.^[1] Most fibroadenomas often undergo self-limited growth and usually stabilize after several years. The clinical diagnosis is mainly based on clinical palpation and ultrasonographic examination, while the golden standard diagnosis is pathological examination. To standardize the clinical diagnosis and treatment of breast fibroadenoma, the Chinese Society of Breast Surgery (CSBrS) conducted a literature review of experts' opinions, and determined the key clinical questions for the clinical practice guideline of breast fibroadenoma. The group evaluated the relevant evidences using the grading of recommendations assessment, development, and evaluation system, and developed the clinical practice guideline for breast fibroadenoma: CSBrS practice guideline 2021, with the aim of providing clinical practice guidance to breast surgeons in China.

Level of Evidence and Recommendation Strength

Level of evidence standard^[2]

Recommendation strength standard^[2]

Recommendation strength review committee

There were 79 voting committee members for these guidelines: 67 from breast surgery departments (84.8%), three from medical oncology departments (3.8%), four from medical imaging departments (5.1%), two from a pathology department (2.5%), one from radiology department (1.3%), and two epidemiologists (2.5%).

Target Audience

Clinicians specializing in breast diseases in China.

Recommendations

Recommendation 1: Diagnosis of fibroadenoma

	Diagnosis of fibroadenoma	Level of evidence	Recommendation strength
1.1	Clinical palpation ^[3]	II	A
1.2	Ultrasonography ^[4-9]	I	A
1.3	Pathology ^[3,10-12]	I	A

Recommendation 2: Surgical treatment

	Surgical treatment	Level of evidence	Recommendation strength
2.1	Indications		
2.1.1	Rapid growth ^[13]	II	A
2.1.2	Large size (>3 cm) ^[13]	II	A
2.1.3	BI-RADS category increased ^[3,13]	I	A
2.1.3	Core needle biopsy suggested with atypical hyperplasia or suspected phyllodes tumor ^[13]	I	A
2.2	Surgical options		
2.2.1	Open excision ^[3]	I	A
2.2.2	Ultrasound-guided VABB ^{[3,14-16]*}	II	A

* For fibroadenomas where VABB is planned, please refer to the Clinical Practice Guidelines for Ultrasound-guided Vacuum-assisted Breast Biopsy for details. BI-RADS: Breast Imaging Reporting and Data System; VABB: Vacuum-assisted breast biopsy.

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Recommendation 3: Non-surgical treatment

	Non-surgical treatment	Level of evidence	Recommendation strength
3.1	Indications		
3.1.1	BI-RADS category 3 ^[3,17]	I	A
3.1.2	Sonographically-typical fibroadenomas in a young patient ^[8,9,18]	II	A
3.2	Follow-up interval		
3.2.1	Every 6 months ^[17]	I	A
3.3	Follow-up method		
3.3.1	Clinical palpation combined with ultrasonography ^[3,17]	I	A
3.3.2	Annual mammography starting at age 40 years ^[17]	I	A

BI-RADS: Breast Imaging Reporting and Data System.

Discussion

Fibroadenoma is the most common benign breast tumor in women. Most fibroadenomas form as a single tumor, and in approximately 15% of patients, multiple tumors are present.^[19] Clinical palpation reveals mostly oval, rubber-like masses with clear boundaries and good mobility. However approximately 25% to 35% of affected patients have negative palpation findings.^[20-22]

The clinical diagnosis of fibroadenoma is mainly based on palpation and imaging examinations, namely ultrasonography, mammography, and magnetic resonance imaging (MRI). The reported that the accuracy of breast ultrasonography in the diagnosis of fibroadenoma is 78.8% to 99.5%.^[4-9] The specificity of mammography for diagnosing of fibroadenoma is 83.9%, which is lower than that for ultrasonography (88.2%),^[2,3] but mammography has outstanding advantages for differentiating malignant from benign calcification. Breast enhanced MRI can further improve the diagnostic accuracy rates for fibroadenomas.^[24] According to the characteristics of the Chinese female mammary gland, the guidelines panel recommends ultrasonography examination first. In patients aged ≥40 years with a mass with suspected microcalcification or not excluded as malignant, mammography is recommended. Considering the economic cost, enhanced MRI is not recommended as a conventional imaging method for diagnosing fibroadenoma. For multiple lesions and an unclear diagnosis after ultrasonography and mammography, MRI can be selected as appropriate.

Pathological examination is the golden standard for diagnosing fibroadenoma. Fine needle aspiration, core needle biopsy, vacuum-assisted breast biopsy, and excision biopsy are all available methods. The reported accuracy of fine needle aspiration cytology for diagnosing fibroadenoma ranges from 36.3% to 91.7%,^[25-28] and the diagnostic accuracy of core needle biopsy can be as high

as 93.4% to 98.3%,^[10,11] with minimal tissue damage. Therefore, the guidelines panel recommends core needle biopsy as the first choice for the pathological diagnosis of fibroadenoma.

The incidence of malignancy in fibroadenoma is very low, therefore, regular follow-up after core needle biopsy diagnosed as fibroadenoma is safe. For Breast Imaging Reporting and Data System (BI-RADS) category 3 fibroadenoma, the guidelines panel recommends clinical palpation combined with ultrasonography examination every 6 months. For patients with stable lesions followed up regularly for 2 years, the follow-up interval may be extended to once every 12 months. For patients ≥40 years old, mammography is recommended according to the breast cancer screening guidelines and the standards of the American College of Radiology.^[17] It is safe not to biopsy of typical fibroadenomas in young women when the clinical and sonographic presentations meet strict criteria. This is because, in these patients, ultrasonography and pathology have good concordance rates, and a missed diagnosis of malignant disease is rare.^[8,9,18]

Open excision is the most effective surgical intervention for fibroadenoma, especially for large tumors. Ultrasound-guided vacuum-assisted breast biopsy is also safe for fibroadenomas of appropriate size and location, especially for patients with high aesthetic requirements.^[3,14-16] However, with larger tumors, the possibility of residual lesions is greater; therefore, ultrasound-guided vacuum-assisted breast biopsy is generally not recommended for tumors larger than 3 cm. Phyllodes tumors are indistinguishable from fibroadenoma with ultrasonography and mammography. Considering that pre-operative biopsy is also insufficient to distinguish phyllodes tumor from fibroadenoma, and there is the possibility of underestimation,^[29-31] referring to the NCCN clinical practice guidelines in oncology for breast cancer, about phyllodes tumor, the CSBrS guidelines panel recommends that tumors larger than 3 cm are an indication for surgical treatment.^[13] Rapid growth is also an indication for surgical treatment. The criteria for rapid growth are: (1) volume growth rate ≥16% per month for patients younger than 50 years, (2) volume growth ≥13% per month for patients ≥50 years, and (3) mean change in dimension over a 6-month interval of >20%.^[32] In addition, an increased BI-RADS classification grade during the follow-up and core needle biopsy suggesting with atypical hyperplasia or suspected phyllodes tumor are also indications for surgical treatment.

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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 CSBrS 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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