

Clinical practice guidelines for visualized percutaneous breast tissue clips: Chinese Society of Breast Surgery (CSBrS) practice guideline 2021

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Breast tissue clip is a kind of tissue marker visible under ultrasound (US), mammogram (MMG), and magnetic resonance imaging (MRI) and could be used to precisely mark the breast lesions and axillary lymph nodes (LN) under US or MMG guidance.^[1] In order to standardize the clinical application of tissue clip, the Chinese Society of Breast Surgery (CSBrS) identified key clinical issues and developed this clinical practice guideline after evaluating the evidence with reference to the GRADE (*ie*, Grading of Recommendations Assessment, Development, and Evaluation) system and the accessibility in clinical practice.

Level of Evidence and Recommendation Strength

Level of evidence standard^[2]

Recommendation strength standard^[2]

Recommendation strength review committee

There were 78 voting committee members for the guideline: 65 breast surgeons (83.3%), four medical oncologists (5.1%), three radiologists (3.9%), two pathologists (2.6%), one radiation therapist (1.3%), and two epidemiologists (2.6%).

Target Audience

Clinicians specializing in breast diseases in China.

Recommendations

Recommendation 1: Indications of tissue clips

	Indications of tissue clips	Level of evidence	Strength of recommendation
1.1	Indications for primary breast lesion		
1.1.1	Non-palpable suspicious breast lesion, for surgical biopsy ^[3]	II	A
1.1.2	Non-palpable breast cancer, for breast-conserving surgery ^[4,5]	I	A
1.1.3	Breast cancer for neoadjuvant therapy and breast-conserving surgery ^[6]	I	A
1.2	Indications for axilla lymph node		
1.2.1	Pathologically confirmed metastatic axillary LN (pN1), for neoadjuvant therapy ^[7]	I	A

Discussion

With the widespread screening for breast cancer, detected nonpalpable breast lesions have been increased.^[16] Clip placement in nonpalpable suspicious breast lesions could

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Recommendation 2: Contraindications of clip placement

	Contraindications to clip placement	Level of evidence	Strength of recommendation
2.1	Concomitant severe systemic disease not to tolerate, psychiatric disorders, or other reasons not to cooperate ^[8,9]	I	A
2.2	Concomitant severe bleeding or coagulation disorders ^[8,9]	I	A
2.3	The presence of breast local infection or adjacent to the breast prosthesis ^[8,9]	I	A

Recommendation 3: Clinical issues for positioning tissue clip

	Clinical issues for positioning tissue clip	Level of evidence	Strength of recommendation
3.1	Number of clips placed		
3.1.1	One placed in the center of primary breast lesion ^[10,11]	II	A
3.1.2	One placed in the center of metastatic axillary LN ^[8,9]	I	A
3.2	Imaging-guided approaches for clip placement		
3.2.1	Ultrasound-guided placement ^[11-13]	I	A
3.2.2	X-ray-guided placement ^[12]	I	A
3.3	Preoperative clip localization methods		
3.3.1	Guide wire ^[9,14]	I	A
3.3.2	Dye ^[15]	I	A
3.3.3	Isotopic tracer ^[12]	I	A
3.4	Intraoperative clip confirmation		
3.4.1	Intraoperative radiography ^[15]	I	A
3.5	Timing of clip placement in neoadjuvant therapy		
3.5.1	Before neoadjuvant therapy following pathological confirmation of primary breast cancer lesion ^[6]	I	A
3.5.2	Before neoadjuvant therapy following pathological confirmation of metastatic axillary LN ^[8,9]	I	A

LN: Lymph nodes.

provide help in follow-up and surgical biopsy.^[3] The expert panel recommended the clip placement in non-palpable breast suspicious lesions as one indication.

Accurate localization of nonpalpable breast cancer is a prerequisite for breast-conserving surgery, whereas clip placement and localization could increase negative margin rate to 90%,^[11] and reduce the secondary resection.^[4,5] The expert panel recommended the clip placement and perioperative poisoning in nonpalpable breast cancer intended for breast-conserving surgery as one indication.

In breast cancer neoadjuvant therapy, the clinical complete remission rate could reach 20% to 57%.^[6,9] Therefore, residual lesion re-localization after neoadjuvant therapy is important. Retrospective studies showed that clip placement at primary breast cancer before neoadjuvant therapy helped localize tumor intraoperatively and improve the negative surgical margin rate.^[6] Besides, the 5-year local recurrence rate was lower in the clipped group than in the control.^[6] The expert panel recommends the clip placement for primary breast cancer in neoadjuvant patients, especially planned for breast-conserving surgery.

Functional axillary LN dissection has received increasing attention recently. The ACOSOG Z1071, MARI, and ILINA trials have shown the feasibility of the targeted axillary dissection (TAD) technique, suggesting that the removal of sentinel and clipped LNs could reflect the axillary LNs status (false negative rate/FNR 2%–7%) and reduce the incidence of postoperative upper limb lymphedema.^[7-9,17] The expert panel recommends clip placement to label the pathologically confirmed metastatic axillary LN (pN1) before neoadjuvant therapy, providing an opportunity for TAD.

The contraindications to US or MMG-guided clip placement for breast lesion and axillary LN should be based on the preoperative evaluation principles of breast lesion and regional LN biopsy, with reference to published exclusion criteria in clinical trials.^[7,8] The expert panel recommends the contraindications for clip placement at Recommendation 2.

US-guided clip placement has been reported to be more accurate than X-ray-guided placement.^[3,12] The expert panel preferred US-guided clip placement, with X-ray-guided placement as an optional method. Regarding the number of clips to be placed, which should balance localization accuracy and medical cost,^[10,11] the expert panel recommended one clip for each primary breast lesion or metastatic axillary LN.

Due to the small size of clips, intraoperative position failure and loss of clips have been reported in 5% to 20% of cases.^[7] Considering the clinical operability and accessibility in China, the expert panel recommended the use of guide wires or dyes for preoperative assisted clip localization, and isotopic tracers could be used when available. Intraoperative resected specimens need to be re-examined, and the expert panel recommends the use of radiographic imaging for intraoperative clip confirmation.

Regarding the timing of clip placement, delayed clip placement in primary breast lesions after 2-cycle of effective neoadjuvant therapy may achieve some health-

economics advantages,^[18] but further confirmation is needed from prospective studies. For metastatic axillary LN, published studies indicated that clip placement needed before neoadjuvant therapy.^[7-9] The expert panel recommends clip placement in pathologically confirmed primary breast cancer and metastatic axillary LN before neoadjuvant therapy.

Appendix 1: Technical guidelines for visualized percutaneous breast tissue clip placement, <http://links.lww.com/CM9/A624>.

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 nonbreast 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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