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Could Intraoperative Frozen Section Replace Preoperative Core Needle Biopsy in Selected Small Breast Lesions? A Hypothesis for Prospective Evaluation

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Rezumat

Ar putea examenul histopatologic extemporaneu înlocui biopsia preoperatorie cu ac gros în cazul leziunilor mamare mici selectate? O ipoteză propusă pentru evaluare prospectivă

Context: Biopsia cu ac gros (core needle biopsy, CNB) rămâne abordarea diagnostică standard pentru leziunile mamare suspecte, oferind confirmarea histologică preoperatorie şi caracterizarea biologică esențială pentru planificarea tratamentului. Totuşi, depistarea tot mai frecventă a cancerelor mamare mici, localizate clinic, ridică întrebarea dacă o biopsie preoperatorie separată este indispensabilă la fiecare pacientă atent selectată, considerată deja candidată pentru intervenție chirurgicală de primă intenție. *Obiectiv:* Explorarea ipotezei conform căreia examenul histopatologic extemporaneu intraoperator ar putea înlocui o CNB preoperatorie separată într-un subgrup strict definit de paciente cu leziuni mamare mici, înalt suspecte, fără adenopatie decelabilă clinic.
Discuție: Un parcurs diagnostic şi terapeutic într-o singură etapă ar putea fi luat în considerare pentru investigare prospectivă atunci când evaluarea multidisciplinară indică faptul că intervenția chirurgicală de primă intenție ar rămâne tratamentul inițial preferat, iar cunoaşterea preoperatorie a biologiei tumorale este puțin probabil să modifice secvența terapeutică. Avantajele potențiale includ reducerea numărului de proceduri separate şi de prezentări în sistemul de sănătate. Cu toate acestea, abordarea propusă prezintă limitări importante, printre care rezultatele neconcludente ale examenului extemporaneu, întârzierea caracterizării statusului receptorilor, posibilitatea unei intervenții chirurgicale suplimentare şi riscul unei secvențe terapeutice inadecvate. CNB preoperatorie rămâne esențială ori de câte ori biologia tumorală poate influența decizia privind tratamentul neoadjuvant.
Concluzie: Examenul histopatologic extemporaneu intraoperator nu trebuie considerat o alternativă consacrată la CNB. Rolul său potențial la paciente înalt selectate justifică o investigare prospectivă comparativă, care să evalueze

acuratețea diagnostică, siguranța oncologică, rezultatele raportate de paciente şi consumul de resurse din sistemul de sănătate.

Cuvinte cheie: examen extemporaneu, biopsie cu ac gros, cancer mamar, cancer mamar incipient, chirurgie mamară

Abstract

Background: Core needle biopsy (CNB) remains the standard diagnostic approach for suspicious breast lesions, providing preoperative histological confirmation and biological characterization essential for treatment planning. However, the increasing detection of small, clinically localized breast cancers raises the question of whether a separate preoperative biopsy is indispensable in every carefully selected patient already considered suitable for upfront surgery. *Objective:* To explore the hypothesis that intraoperative frozen-section examination could potentially replace a separate preoperative CNB in a narrowly defined subgroup of patients with small, highly suspicious, clinically node-negative breast lesions.
Discussion: A one-stage diagnostic and therapeutic pathway might be considered for prospective investigation when multidisciplinary assessment indicates that upfront surgery would remain the preferred initial treatment and preoperative tumour biology is unlikely to alter therapeutic sequencing. Potential advantages include fewer separate procedures and healthcare encounters. Nevertheless, the proposed approach presents important limitations, including inconclusive frozen-section findings, delayed receptor characterization, possible additional surgery, and the risk of inappropriate treatment sequencing. Preoperative CNB remains essential whenever tumour biology may influence neoadjuvant treatment decisions.
Conclusion: Intraoperative frozen-section examination should not be considered an established alternative to CNB. Its potential role in highly selected patients warrants prospective comparative investigation to assess diagnostic accuracy, oncological safety, patient-reported outcomes, and healthcare resource use.

Keywords: frozen section, core needle biopsy, breast cancer, early breast cancer, breast surgery

Introduction

Core needle biopsy (CNB) is currently regarded as the standard diagnostic procedure for the histopathological evaluation of suspicious breast lesions. Its widespread adoption in contemporary breast cancer management is supported by its high diagnostic accuracy, minimally invasive nature, and ability to provide sufficient tissue for both histopathological examination and immunohistochemical characterization, thereby facilitating therapeutic planning before definitive surgery (1-4).

When performed under appropriate imaging guidance, CNB demonstrates excellent diagnostic performance, with reported sensitivity exceeding 90% and specificity approaching 100%. Compared with fine-needle aspiration cytology, it offers superior diagnostic reliability and has therefore become the preferred technique for tissue diagnosis of suspicious breast lesions. In addition, preoperative histological confirmation may reduce the need for diagnostic surgical excision and allows multidisciplinary treatment planning, including consideration of neoadjuvant systemic therapy whenever indicated (1,3,5).

Despite these well-established advantages, advances in breast imaging, earlier detection through screening programmes, and the increasing diagnosis of small localized breast cancers have modified the clinical profile of many patients undergoing breast surgery. Consequently, it may be appropriate to reconsider whether preoperative CNB is indispensable in every patient with early breast cancer, particularly in those who are already candidates for primary surgical treatment and for whom neoadjuvant therapy is not expected to modify the initial therapeutic approach (2,6,7).

Intraoperative frozen section has long represented a reliable pathological technique capable of providing immediate histological diagnosis during surgery. Although its routine diagnostic role has progressively declined following the widespread implementation of image-guided CNB, frozen section remains available in many breast units and continues to provide rapid intraoperative confirmation of malignancy when required. Whether this established technique could still have a role in carefully selected patients with early breast cancer has received relatively limited attention in contemporary clinical practice (2).

Importantly, the rationale for reconsidering this pathway does not arise from evidence that CNB is

inadequate, but from the possibility that its clinical contribution may differ according to the therapeutic context. In patients for whom histological subtype and biomarker status may determine the use of neoadjuvant systemic therapy, preoperative tissue diagnosis remains essential for treatment planning (6-7). Conversely, a narrower clinical question arises in patients with a small, highly suspicious, clinically node-negative lesion for whom upfront surgery would already represent the anticipated initial treatment. In this setting, it remains uncertain whether a separate preoperative tissue-sampling procedure is indispensable in every case or whether, under carefully predefined conditions, histological confirmation could be integrated into the definitive surgical procedure.

The purpose of this Hypothesis and Theory article is not to challenge the established role of core needle biopsy as the current standard of care. Rather, it aims to discuss whether frozen section may represent a reasonable alternative in highly selected patients with small breast cancers who are already scheduled for upfront surgery and in whom preoperative tumour biology is unlikely to alter the initial surgical strategy. This perspective should be regarded as a hypothesis intended to stimulate further clinical discussion and prospective evaluation rather than as a proposal to modify current guideline recommendations.

Could Frozen Section Still Have a Role in Selected Patients?

Although core needle biopsy remains the recommended diagnostic approach for the vast majority of patients with suspected breast cancer, whether a separate preoperative CNB is required in every carefully selected clinical scenario remains a question worthy of investigation. The objective is not to replace the established role of CNB, but rather to explore whether certain patients who are already candidates for primary surgery could safely proceed directly to definitive surgical excision with intraoperative pathological confirmation by frozen section.

Approximately 70–80% of invasive breast cancers belong to the luminal subtype, while an increasing proportion of breast malignancies are currently diagnosed at an early stage through population screening programmes. Consequently, many women present with small, clinically localized tumours that are managed with upfront surgery rather than neoadjuvant systemic treatment (7-8). The potential relevance of such an approach is therefore greatest when multidisciplinary assessment indicates that upfront surgery would remain the preferred initial treatment and when preoperative tumour biology is unlikely to alter therapeutic sequencing.

In this particular clinical setting, patients presenting with clinically node-negative T1 tumours, including T1a (>0.1–0.5 cm), T1b (>0.5–1.0 cm), and selected T1c (>1.0–2.0 cm) lesions—may represent a subgroup in whom preoperative CNB does not necessarily modify the initial surgical management, provided that no indication exists for neoadjuvant treatment (7,9,10). Importantly, very small lesions may pose particular challenges for frozen-section examination, as freezing artefacts and tissue consumption may compromise the material available for definitive histopathological assessment and subsequent immunohistochemical characterization. Therefore, any prospective evaluation should incorporate predefined criteria regarding lesion size, tissue adequacy, and the preservation of sufficient material for permanent sections and biomarker assessment.

For these carefully selected patients, intraoperative frozen section may provide immediate histopathological confirmation of malignancy while allowing completion of the planned surgical procedure during the same operative session. Such an approach has the potential to avoid a separate diagnostic intervention before surgery without compromising intraoperative pathological confirmation. Importantly, this strategy should only be considered when preoperative imaging findings are highly suggestive of malignancy, the patient is already scheduled for surgical treatment, and multidisciplinary evaluation has excluded any anticipated benefit from preoperative systemic therapy.

It should be emphasized that this proposal is intended for a highly selected subgroup of patients and should not be extrapolated to all breast cancers (*Fig. 1*).

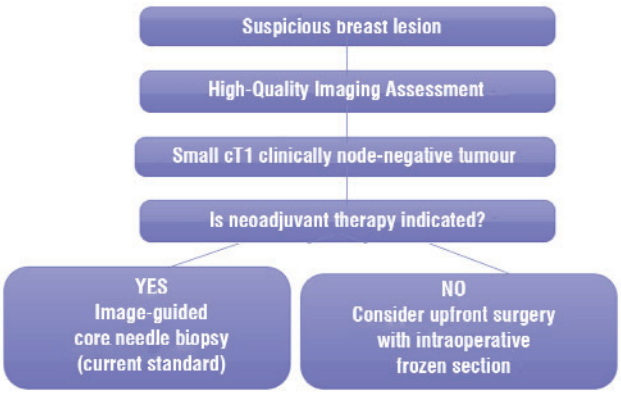


Figure 1. Proposed clinical decision pathway

Importantly, treatment sequencing in small triple-negative breast cancers is not uniform across contemporary guidelines. According to the 2024 French National Cancer Institute (INCa) recommendations, upfront surgery is recommended for node-negative TNBC ≤1 cm, whereas for T1cN0 tumours >1 cm and <2 cm, the use of neoadjuvant chemotherapy should be discussed on an individual basis within a multi-disciplinary tumor board, taking into account the feasibility of breast-conserving surgery, tumour characteristics including TILs and Ki-67, as well as patient age and comorbidities (Institut National du Cancer, 2024) (11).

Thus, selected patients with small cT1cN0 triple-negative tumours should not automatically be considered candidates for neoadjuvant treatment; however, preoperative CNB remains essential whenever tumour biology is expected to influence treatment sequencing. HER2-positive tumours exceeding 20 mm, locally advanced breast cancer, inflammatory breast cancer, and other clinical scenarios in which preoperative biological characterization may determine therapeutic sequencing should continue to undergo image-guided CNB before treatment planning (7,9,10).

Accordingly, rather than questioning the value of CNB, this perspective seeks to identify whether a limited subgroup of women with early breast cancer could potentially benefit from a simplified diagnostic pathway integrating histological confirmation and definitive surgery into a single operative procedure. Whether such an approach is feasible, safe, and clinically advantageous remains to be determined through appropriately designed prospective comparative studies. A critical limitation of such a pathway is the possibility of an inconclusive intraoperative diagnosis. Although frozen-section examination can achieve high diagnostic accuracy in breast pathology, diagnostic discrepancies and deferred diagnoses remain possible, particularly because of sampling limitations, freezing artefacts, and histological features that may require permanent sections or immunohistochemical evaluation (12-13). In such cases, the absence of definitive intraoperative confirmation of malignancy should not prompt completion of cancer-directed surgery on the basis of clinical suspicion alone. The excised specimen should instead undergo standard permanent paraffin-embedded histopathological examination, supplemented by immunohistochemistry when required, and subsequent management should be determined after definitive pathological diagnosis. Furthermore, frozen-section findings should be regarded as preliminary and should not substitute for definitive histopathological assessment, including tumour grading and receptor characterization, which may influence subsequent surgical and systemic treatment decisions.

Consequently, the proposed one-stage pathway would not eliminate the possibility of a second procedure in all patients; rather, this possibility represents an inherent limitation that should be explicitly discussed with patients during preoperative counselling.

Axillary management represents an additional practical consideration in the proposed pathway. When sentinel lymph node biopsy (SLNB) remains indicated, sentinel node mapping could be performed during the same operative session as breast surgery, using an established mapping technique according to institutional expertise and availability. Conventional approaches include technetium-99m radiocolloid, blue dye, or their combination, while indocyanine green fluorescence has emerged as an effective alternative mapping method (14). Importantly, the proposed pathway does not imply that SLNB should be routinely performed in every patient considered for upfront surgery. Contemporary guidelines support omission of SLNB in carefully selected patients with small, clinically node-negative breast cancers when nodal information is unlikely to alter subsequent treatment decisions. Therefore, the decision to perform SLNB should remain individualized and consistent with current guideline recommendations. When intraoperative assessment of a sentinel node is performed but remains inconclusive, definitive axillary management should be deferred until permanent histopathological examination rather than proceeding automatically to more extensive axillary surgery (6).

Potential Advantages and Practical Considerations

If carefully selected patients could safely proceed directly to surgical excision with intraoperative frozen section, several potential advantages deserve consideration. First, this approach could eliminate the need for a separate preoperative invasive diagnostic procedure, allowing histopathological confirmation and definitive surgical treatment to be completed during the same operative session. For appropriately selected patients already scheduled for surgery, this may simplify the diagnostic pathway by avoiding a separate interval awaiting preoperative histopathological results and providing immediate intraoperative diagnostic information, thereby potentially reducing the time between initial diagnostic assessment and definitive treatment (2). Reducing the number of separate diagnostic procedures and healthcare

encounters could also potentially decrease resource use and associated costs; however, whether a one-stage pathway provides an economic advantage over the conventional CNB-first approach would require formal health-economic evaluation.

Technical feasibility may also vary according to lesion characteristics and anatomical location. Image-guided CNB can be more technically demanding for small or deeply located lesions, particularly when lesions lie close to the chest wall or adjacent critical structures, including the axillary region. Although modifications in biopsy technique and needle selection can often facilitate safe tissue sampling in these circumstances, lesion accessibility remains an important practical consideration when selecting the most appropriate biopsy approach (4,15).

A further consideration relates to the inherent limitations of core needle biopsy. Although its diagnostic performance is excellent, false-negative results continue to be reported, even in experienced centres. Previous studies have demonstrated false-negative rates ranging from approximately 3% to 5%, with even higher rates reported when image guidance is suboptimal or lesions are inadequately sampled (16).

More recent systematic evidence likewise confirms that false-negative results remain possible with CNB, although diagnostic performance is generally high and varies according to biopsy technique and lesion characteristics (17). Very small lesions may present an additional sampling challenge, and alternative image-guided techniques, such as vacuum-assisted biopsy, may be preferred in selected cases to reduce the risk of insufficient or non-representative sampling (4). Although these events are uncommon, they may delay definitive diagnosis and subsequent treatment.

Core needle biopsy is generally performed under local anaesthesia and has a well-established safety profile; nevertheless, as a separate invasive procedure, it may be associated with transient pain or discomfort (18). Procedure-related complications are uncommon and are usually minor, including bruising, bleeding, or hematoma formation, while infectious complications are rare (1). Although these events generally resolve without significant clinical consequences, complications requiring additional treatment may occasionally complicate the interval between biopsy and definitive surgery. Procedure-related complications are uncommon and are usually minor, including bruising, bleeding, or hematoma formation, while infectious complications are rare (1). Rare complications such as hemopneumo-thorax have also been described in the literature (19). Likewise, isolated reports have documented tumour implantation along the biopsy tract following CNB, although this phenomenon appears to be extremely uncommon and its clinical significance remains uncertain (20-21). These complications are uncommon and, in the case of biopsy-tract tumour cell displacement, the clinical relevance remains uncertain. They should therefore not be interpreted as arguments against the routine use of CNB, whose overall safety profile is well established. Rather, they illustrate that the comparison between a conventional CNB-first pathway and a potential one-stage surgical pathway should consider not only diagnostic performance but also the number and nature of procedures experienced by the patient (*Table 1*).

From the patient's perspective, undergoing two separate procedures, first a diagnostic biopsy and subsequently definitive surgery, may also contribute to increased emotional burden while prolonging the

Table 1. Potential advantages and limitations of frozen section compared with core needle biopsy in carefully selected patients with early breast cancer

Aspect	Core Needle Biopsy	Frozen Section
Histopathological diagnosis	Preoperative	Intraoperative
Immunohistochemical assessment (ER, PR, HER2)	Available before surgery	Usually available after permanent pathology
Number of procedures	Diagnostic biopsy followed by surgery	Potentially one operative session; additional surgery may be required
Time to histological diagnosis	Several days	Immediate during surgery
Neoadjuvant treatment planning	Fully supported	Not appropriate when preoperative tumour biology is required
False-negative sampling	Low but reported	Diagnostic limitations remain possible, including sampling errors and inconclusive findings
Procedure-related complications	Minor complications may occur;	Surgical risks remain; additional procedures may be necessary rare serious complications reported
Appropriate candidates	Most patients with suspected breast cancer	Carefully selected patients with small cT1 node-negative tumours already planned for upfront surgery
Current guideline recommendation	Standard of care	Hypothesis requiring prospective evaluation

period of diagnostic uncertainty. Previous studies have highlighted the importance of providing patients with balanced information regarding breast biopsy procedures and their potential psychological impact (22). For selected women who are already committed to primary surgical treatment, combining diagnosis and definitive surgery into a single procedure may therefore represent an aspect worthy of further investigation.

Nevertheless, these potential advantages should always be balanced against the well-recognized benefits of preoperative CNB. Histological confirmation before surgery provides essential information regarding tumour subtype and receptor status, facilitating multidisciplinary treatment planning and identifying patients who would benefit from neoadjuvant systemic therapy (2). Consequently, frozen section should not be regarded as a replacement for CNB but rather as a potential alternative in highly selected clinical circumstances where preoperative biological characterization is unlikely to modify the initial therapeutic approach.

At present, the available evidence remains insufficient to recommend any modification of current clinical practice. The concept presented in this article should therefore be considered hypothesis-generating. Well-designed prospective comparative studies evaluating diagnostic accuracy, patient-reported outcomes, healthcare costs, surgical workflow, and oncological safety are required before this approach can be incorporated into routine clinical practice.

Proposed Framework for Prospective Evaluation

A prospective evaluation of this hypothesis should therefore focus on a clearly predefined, highly selected population rather than on patients with breast cancer in general. Eligible patients could include women with small, highly suspicious cT1, clinically node-negative breast lesions for whom multidisciplinary assessment has already established upfront surgery as the appropriate initial treatment and in whom preoperative tumour biology is not expected to alter therapeutic sequencing. A comparative study could evaluate the proposed one-stage pathway against the conventional CNB-first pathway, with particular attention to diagnostic concordance, the frequency of deferred or inconclusive intraoperative diagnoses, need for additional surgical procedures, time to definitive treatment, patient-reported outcomes, healthcare resource use, and oncological safety. Such evidence would be necessary to determine whether omission of preoperative CNB in this narrowly defined population offers any meaningful clinical advantage without compromising diagnostic or therapeutic decision-making.

Conclusion

Core needle biopsy remains the standard diagnostic approach for suspicious breast lesions and provides essential preoperative histological and biological information for contemporary multidisciplinary treatment planning. The present discussion does not question this established role. Rather, it considers whether a separate preoperative biopsy is indispensable in every patient, particularly when a small, highly suspicious, clinically node-negative lesion has been identified and upfront surgery would already represent the anticipated initial treatment.

The question, therefore, is not whether core needle biopsy should be abandoned, but whether it is indispensable in every patient with a small, highly suspicious, clinically node-negative breast lesion. In carefully selected cases, an alternative one-stage diagnostic and therapeutic pathway incorporating intraoperative frozen-section assessment may merit prospective evaluation. Such an approach, however, must account for the possibility of inconclusive intraoperative findings, the potential need for permanent histopathology and subsequent surgery, and appropriate management of the axilla.

At present, the available evidence is insufficient to support a change in established clinical practice. Prospective comparative studies are required to determine whether this proposed pathway can reduce unnecessary procedural steps or time to definitive treatment without compromising diagnostic accuracy, oncological safety, treatment planning, or patient outcomes. Until such evidence is available, this concept should be regarded as a hypothesis for clinical investigation rather than an alternative standard of care.

Conflicts of Interest

The authors declared no potential conflicts of interest.

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