HOLOGIC

Reducing DCIS underestimation

How vacuum-assisted breast biopsy improves diagnostic accuracy

Summary

Ductal carcinoma *in situ* (DCIS) is often underestimated with core needle biopsy (CNB), leading to misdiagnosis and unnecessary treatment.

- Vacuum-assisted breast biopsy (VABB) improves accuracy, reducing underestimation rates by over 53 %, or 58 % for sterotactic-guided VABB, compared to CNB.
- VABB lowers the need for repeat biopsies by 22 % and increases diagnostic consistency.
- Fewer repeat procedures and surgeries reduce overall costs and ease pressure on healthcare resources.
- VABB offers better value per diagnosis, making it a cost-effective choice in breast cancer care.

Introduction

DCIS is a stage 0, non-invasive proliferation of neoplastic luminal cells confined to the ductal-lobular system of the breast, without evidence of invasion through the basement membrane.[1] DCIS is typically identified on a mammogram during routine breast screening, and – mostly due to increased rates of screening – now accounts for around 25 % of new breast cancer diagnoses. DCIS can progress to invasive cancer, although the rate at which this occurs remains unclear, with current estimates ranging from 25-60 % of cases.[2] Distinguishing DCIS from early invasive breast cancer can be challenging due to their similar appearance on mammograms, and because biopsies often fail to accurately diagnose the severity of a lesion.[3] However, the distinction is important to prevent under- or overtreatment of the patient, and because the link between DCIS and progression to invasive cancer, and the associated risk factors, are not well understood. This paper investigates the challenge of diagnosing DCIS, and describes how using VABB can help to reduce DCIS underestimation and improve patient outcomes.

The clinical challenge: DCIS underestimation

Underestimation of DCIS during initial diagnosis – with the lesion later upgraded after pathological examination of the surgical specimen – presents a significant challenge in clinical practice and can complicate treatment decisions.[3] CNB, the standard diagnostic method, samples only a portion of any lesion and may miss areas of microinvasion or under-represent high-grade features.[4] A previous meta-analysis showed that approximately 26 % of cases initially diagnosed as DCIS via core biopsy are upstaged to invasive cancer following surgical excision and pathology.[5]

Patients diagnosed with DCIS are typically treated by either wide local excision with radiotherapy, or mastectomy. However, due to concerns regarding DCIS underestimation, routine sentinel lymph node biopsy may also be necessary in patients with DCIS diagnosed by CNB.[3] This axillary dissection is often accompanied by complications such as pain, numbness and arm swelling, increasing discomfort for the patient, but may often be unnecessary.[3] The diagnostic uncertainty associated with CNB highlights the need for more precise preoperative assessment to guide appropriate treatment strategies, and minimise the risks of incorrect disease management and the associated patient distress.

Ductal carcinoma *in situ* (DCIS) is recognised by the World Health Organization (WHO) Classification of Tumours as a non-invasive neoplastic epithelial proliferation confined to the mammary ducts and lobules.[6] Accurate diagnosis is critical as up to 20-30 % of cases may harbour undetected invasive components. Underestimation – often due to limitations in imaging and CNB sampling – can result in inadequate treatment planning, leading to additional surgery, which increases costs and patient anxiety.

VABB's role in reducing DCIS underestimation

While both CNB and VABB remain the preferred methods for preoperative diagnosis of breast lesions, the latter has emerged as a valuable tool in addressing the issue of DCIS underestimation by providing larger and more representative tissue samples compared to traditional CNB. VABB uses a vacuum-powered device to obtain multiple, contiguous samples from a single insertion, allowing more comprehensive sampling of the lesion and its surrounding tissue. The technique significantly lowers the rate of DCIS underestimation, with upstaging rates to invasive cancer following surgical excision markedly reduced compared to standard CNB. This is highlighted in multiple studies, including:

- Badan *et al*., who found that the underestimation rate for DCIS using CNB was 28.57 %, compared to 14.28 % with VABB[7];
- Yashima *et al*. found the upgrade rate from high-risk to malignant lesions was significantly higher for CNB (26.3 %) than for VABB (12.5 %)[8];
- Sim *et al*. showed in a large analysis that the upgrade rate was significantly lower with the use of VABB (19.9 %) than CNB (26%).[9]

These results corroborate data in the wider literature, implying that the choice of biopsy method directly influences diagnostic accuracy. The ability to analyse larger volumes of lesion tissue with VABB may help to minimise sampling errors, leading to a reduced frequency of underestimation and the need for repeat biopsy.[10]

Hologic commissioned a third party to perform a systematic literature review and meta-analysis to gain detailed insights into the clinical effectiveness of VABB. Of the 959 papers that were identified as relevant, 97 were included in the final analysis based on the PICOS model (Annex 1), with a selection of the results shown below.[11]

- Patients biopsied with VABB had a **53 % decreased risk in DCIS underestimation** compared to patients screened with CNB (RR: **0.47** (0.39-0.58), p<0.01).
- When using stereotactic-guided VABB, the risk of DCIS underestimation is **decreased by 58 % compared to CNB (RR: 0.42 (0.30-0.60), p<0.01) and 45 % compared to stereotactic-guided CNB (RR: 0.55 (0.42-0.72), p<0.01).**
- VABB results in a **22 % decreased risk for repeat biopsy** compared to CNB (RR: **0.78** (0.69-0.88), p<0.01).
- **Concordance rate is increased by 7 % when** using VABB over CNB (RR: **1.07** (1.04-1.11), p<0.01).

Comparing biopsy techniques: CNB vs VABB

The heterogeneous nature of breast lesions results in varying histological findings from different areas of a mass, suggesting that sampling part but not all of a lesion may miss certain histological components.[12] It is therefore possible for the core of the lesion, which is targeted by CNB, and the surrounding area to differ histologically.[13] As previously mentioned, VABB may help to address this issue by enabling the collection of larger tissue samples, improving the breadth of cell types collected. In addition, VABB offers several key benefits to clinicians and pathologists, including:

- less invasive for the patient as the needle remains in the breast throughout the biopsy, eliminating the need to repeatedly re-target the needle for sampling;
- only one skin puncture is required, making the biopsy more efficient and saving time for both staff and the patient;
- samples can be taken from different sides of the lesion, or the entire lesion can sometimes be removed, with no further surgical procedures required if it is diagnosed as benign;
- the vacuum function prevents the lesion from moving during aspiration, whereas it can sometimes slip during CNB as a result of the puncture;
- vacuum and irrigation also improve the quality of the sample, as blood is aspirated and more tissue can be sampled;
- the overall costs are offset by improved efficiency and reduced need for additional follow-up procedures due to its higher accuracy, helping to alleviate the burden on healthcare resources and staff.

In addition to these clinical benefits, VABB has several advantages for the patient compared to CNB. Firstly, it is a less invasive procedure, with CNB requiring multiple needle insertions – as well as emitting more noise – increasing patient discomfort and anxiety.[13] This is especially relevant when the procedure is performed on more sensitive areas, such as the nipple, the thoracic wall and the axillary region.[14] Despite using lower gauge needles, VABB also results in less pain experienced by women,[15] and is considered a safe and efficient method, with high patient acceptance and comparable rates of minor complications.[16] Additionally, several studies have concluded that VABB is a highly sensitive method (Table 1), with improved diagnostic accuracy resulting in fewer repeat biopsies and follow-up examinations.[17] Grady *et al*. concluded that this contributed to a lower cost per diagnosis, suggesting that VABB can be a more cost-effective solution compared to CNB.[18]

Study	Sensitivity of VABB (%)
Thakkar (Popat) *et al*[19]	96
Safioleas *et al*[20]	98.2
Amorim *et al*[21]	91.7
Yu *et al*[22]	98.1
Kettritz *et al*[23]	99

Table 1: Sensitivity of VABB found in multiple studies.

Conclusion

VABB represents a significant improvement in the diagnostic management of DCIS, offering a cost-effective, accurate and comprehensive sampling method that effectively reduces the risk of underestimation. By providing larger, contiguous tissue samples, it improves the detection of invasive components that may be missed by standard CNB, allowing more precise treatment planning and reducing the need for additional surgical intervention. Incorporating this technique into routine clinical practice – particularly for lesions with high-risk features or radiological-pathological discordance – enhances diagnostic confidence, reduces costs associated with unnecessary procedures or overtreatment, optimises patient outcomes, and minimises the psychological and physical burdens associated with diagnostic uncertainty. VABB should be considered a key tool in improving the accuracy of DCIS diagnosis.

Annex 1

The PICOS model acts as a framework for the eligibility criteria in systematic reviews of literature. In this review, the components listed below were used to search PubMed and Cochrane Library to identify relevant studies.

Components	
Patients / population	**Women with suspected breast cancer** (symptomatic / non-symptomatic: no restriction regarding age or country)
Intervention	Vacuum-assisted breast biopsy
Comparison / control	(i) Core needle biopsy and (ii) fine needle aspiration
Outcomes	• ADH underestimation rate • DCIS underestimation rate • Underestimation rates in general (not clearly assignable to ADH or DCIS underestimation rate) • Repeat biopsy rate • Concordance rate • (Micro)calcification retrieval rate • Sensitivity* • Specificity* • Complications (haematoma, bleeding, infection, pain, ...) • Mortality • Morbidity • Quality of life • Workflow efficacy (time under compression, time period for one biopsy) * Also searched for positive predictive value, negative predicted value, false-negative rate, false-positive rate, area under the curve to collect all data allowing to have a full set of true negatives, true positives, false negatives, and false positives.
Study design(s)	Comparative studies (single-arm studies were excluded)

References

1. Hanna WM, Parra-Herran C, Lu FI, Slodkowska E, Rakovitch E, Nofech-Mozes S. Ductal carcinoma in situ of the breast: an update for the pathologist in the era of individualized risk assessment and tailored therapies. *Mod Pathol*. 2019;32(7):896-915.
2. Wang J, Li B, Luo M, Huang J, Zhang K, Zheng S, *et al*. Progression from ductal carcinoma in situ to invasive breast cancer: molecular features and clinical significance. *Signal Transduct Target Ther*. 2024;9(1):83.
3. Park KW, Kim SW, Han H, Park M, Han BK, Ko EY, *et al*. Ductal carcinoma in situ: a risk prediction model for the underestimation of invasive breast cancer. *NPJ Breast Cancer*. 2022;8(1):8.
4. Si J, Yang B, Guo R, Huang N, Quan C, Ma L, *et al*. Factors associated with upstaging in patients preoperatively diagnosed with ductal carcinoma *in situ* by core needle biopsy. *Cancer Biol Med*. 2019;16(2):312-318.
5. Brennan ME, Turner RM, Ciatto S, Marinovich ML, French JR, Macaskill P, *et al*. Ductal carcinoma in situ at core-needle biopsy: meta-analysis of underestimation and predictors of invasive breast cancer. *Radiology*. 2011;260(1):119-28.
6. Tan PH, Ellis I, Allison K, Brogi E, Fox SB, Lakhani S, *et al*. WHO Classification of Tumours Editorial Board. The 2019 World Health Organization classification of tumours of the breast. *Histopathology*. 2020;77(2):181-185.
7. Badan GM, Roveda Júnior D, Piato S, Fleury Ede F, Campos MS, Pecci CA, *et al*. Diagnostic underestimation of atypical ductal hyperplasia and ductal carcinoma in situ at percutaneous core needle and vacuum-assisted biopsies of the breast in a Brazilian reference institution. *Radiol Bras*. 2016;49(1):6-11.
8. Yashima Y, Fujioka T, Kubota K, Mori M, Sato A, Oda G, *et al*. Comparison of the clinical and pathological characteristics of ultrasound-guided biopsy for breast masses and non-mass lesions between 16-gauge spring-loaded core needle biopsy and 12-gauge spring-loaded vacuum-assisted biopsy. *J Med Ultrason* (2001). 2023;50(2):205-212.
9. Sim YT, Litherland J, Lindsay E, Hendry P, Brauer K, Dobson H, *et al*. Upgrade of ductal carcinoma in situ on core biopsies to invasive disease at final surgery: a retrospective review across the Scottish Breast Screening Programme. *Clin Radiol*. 2015;70(5):502-6.
10. Alberta Heritage Foundation for Medical Research. Image-guided vacuum-assisted breast biopsy for suspicious, non-palpable breast lesions. 2005 Aug. Report No.: TN 50.
11. Hologic. Data on file. MISC-10553-EUR-2101 Rev 001- Core Value Dossier.
12. Morris EA, Liberman L, Trevisan SG, Abramson AF, Dershaw DD. Histologic heterogeneity of masses at percutaneous breast biopsy. *Breast J.* 2002;8(4): 187-91.
13. Park HL, Hong J. Vacuum-assisted breast biopsy for breast cancer. *Gland Surg*. 2014 May;3(2):120-7.
14. Park HL, Kim LS. The current role of vacuum assisted breast biopsy system in breast disease. *J Breast Cancer.* 2011;14(1):1-7.
15. Szynglarewicz B, Matkowski R, Kasprzak P, Forgacz J, Zolnierek A, Halon A, *et al*. Pain experienced by patients during minimal-invasive ultrasound-guided breast biopsy: vacuum-assisted vs core-needle procedure. *Eur J Surg Oncol*. 2011;37(5):398-403.
16. Monib S, Mukerji S, Narula S. Vacuum-Assisted Breast Biopsy System: No Innovation Without Evaluation. *Cureus*. 2021;13(1):e12649.
17. Philpotts LE, Shaheen NA, Carter D, Lange RC, Lee CH. Comparison of rebiopsy rates after stereotactic core needle biopsy of the breast with 11-gauge vacuum suction probe versus 14-gauge needle and automatic gun. *AJR Am J Roentgenol*. 1999;172(3):683-7.
18. Grady I, Vasquez T, Tawfik S, Grady S. Ultrasound-Guided Core-Needle Versus Vacuum-Assisted Breast Biopsy: A Cost Analysis Based on the American Society of Breast Surgeons' Mastery of Breast Surgery Registry. *Ann Surg Oncol*. 2017;24(3):676-682.
19. Thakkar (Popat) PB, Karbhari A, Shetty N, Gala K, Haria P, Katdare, A, *et al*. Safety and Efficacy of Vacuum-Assisted Breast Biopsies under Ultrasound and Stereotactic Guidance. *J Clin Interv Radiol ISVIR*. 2023;7:172-178.
20. Safioleas PM, Koulocheri D, Michalopoulos N, Liacou P, Flessas I, Nonni A, *et al*. The value of stereotactic vacuum assisted breast biopsy in the investigation of microcalcifications. A six-year experience with 853 patients. *J BUON*. 2017;22(2):340-346.
21. Amorim A, Mattar A, Antonini M, Lopes RC, Damous L, Gebrim LH, *et al*. Abstract PO5-07-09: Accuracy of stereotactic vacuum-assisted breast biopsy for investigating suspicious calcifications in 2.021 patients in a public hospital in Brazil. *Cancer Res*. 2024;84(9_Supplement):PO5-07-09.
22. Yu YH, Liang C, Yuan XZ. Diagnostic value of vacuum-assisted breast biopsy for breast carcinoma: A meta-analysis and systematic review. *Breast Cancer Res Treat*. 2010;120(2):469-479.
23. Kettritz U, Rotter K, Schreer I, Murauer M, Schulz-Wendtland R, Peter D, *et al*. Stereotactic vacuum-assisted breast biopsy in 2874 patients: a multicenter study. *Cancer*. 2004;100(2):245-51.