New Pulse Biopsy Device Safe and Effective in Challenging Cases of Axillary Biopsies: Subgroup Analysis of Initial PULSE Data for Lymph Nodes of Small Size and Difficult Anatomic Location

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2022 Disclosures

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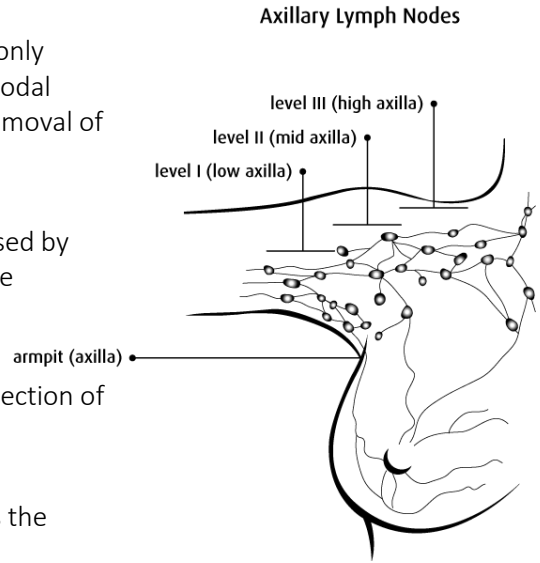
Background

- It is the standard of care in Germany for women with suspected or confirmed breast cancer to undergo ultrasound of the ipsilateral axilla prior to surgery in order to detect nodal metastatic disease.
- Women who have abnormal lymph nodes on axillary ultrasound undergo tissue sampling commonly performed with core needle biopsy (14G) under local anaesthetic. Women with proven axillary nodal metastases will then usually undergo axillary node clearance at the same operation as surgical removal of the primary tumour.
- The number of women who need to undergo more than one operation can therefore be minimised by maximising the number of women with axillary metastatic disease in whom this diagnosis is made preoperatively.
- Increasing the volume of tissue removed may increase the diagnostic yield and sensitivity for detection of metastatic deposits [1].
- Due to the vicinity of the lymph nodes to blood vessels and nerves, it poses challenges and limits the practicability of currently used biopsy devices [2].



[1] Britton PD, Provenzano E, Barter S, Gaskarth M, Goud A, Moyle P, et al. Ultrasound guided percutaneous axillary lymph node core biopsy: How often is the sentinel lymph node being biopsied? Breast 2009;18:13–6. doi:10.1016/j.breast.2008.09.003.
[2] Gruber I, Hahn M, Fehm T et al. Relevance and methods of interventional breast sonography in preoperative axillary lymph node staging. Ultraschall Med 2012, 33(4):337-343.

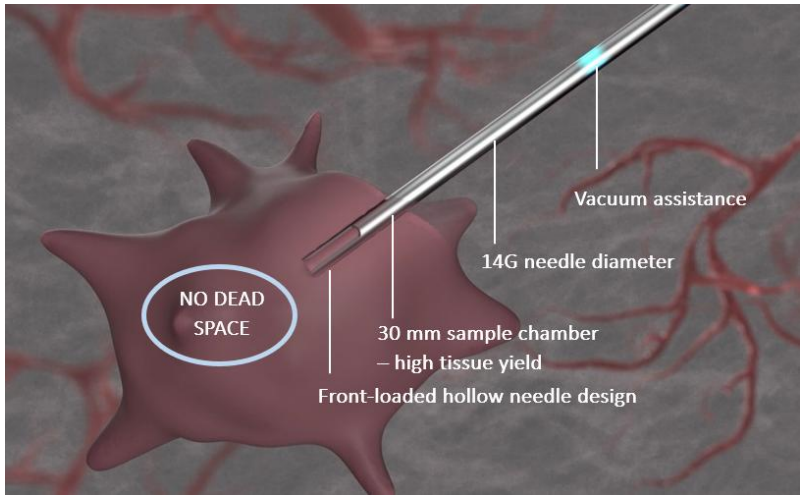
Purpose

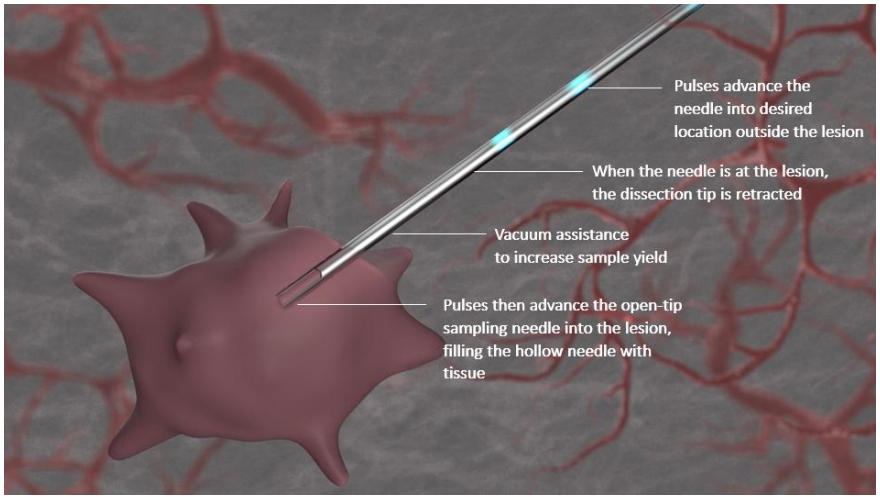
- A new 14G open-tip vacuum-assisted needle (NeoNavia biopsy system, NeoDynamics, Sweden) intended for increased tissue yield and controlled needle insertion has been developed.
- It has shown higher tissue-yield in bench models compared to core needle [1] and promising first results in the axillary lymph nodes [2][3].
- Purpose is to document the performance characteristics of the NeoNavia biopsy device in the axillary lymph nodes and provide basic insights into the complexity of axillary biopsy procedures.

[1] Schässburger K-U, Paepke S, Saracco A, Azavedo E, Ekström C, Wiksell H. High velocity pulse biopsy device enables controllable and precise needle insertion and high yield tissue acquisition. Physica Medica. 2018;46:25-31. doi:10.1016/j.ejmp.2017.12.014
[2] Lee J, Bishop B, Allen S. British Society of Breast Radiology Annual Scientific Meeting 2017. Breast Cancer Research. 2017;19:18-18. doi:10.1186/s13058-017-0903-9
[3] Ohlinger R, Alwafai Z, Lenz F, Möller S, Zygmunt M, Paepke S. Initial experience with novel micro-pulse biopsy system in axillary lymph node. 39. Jahrestagung der Deutschen Gesellschaft für Senologie. 2019. doi:10.1055/s-0039-1687934

Materials and methods

The 14G open-tip sampling needle (FlexiPulse) features a front-loaded, open-tip sampling needle and a retractable trocar. This needle design is especially suited for challenging biopsy cases such as small lesions, lesions located near the skin and the axillary lymph nodes.





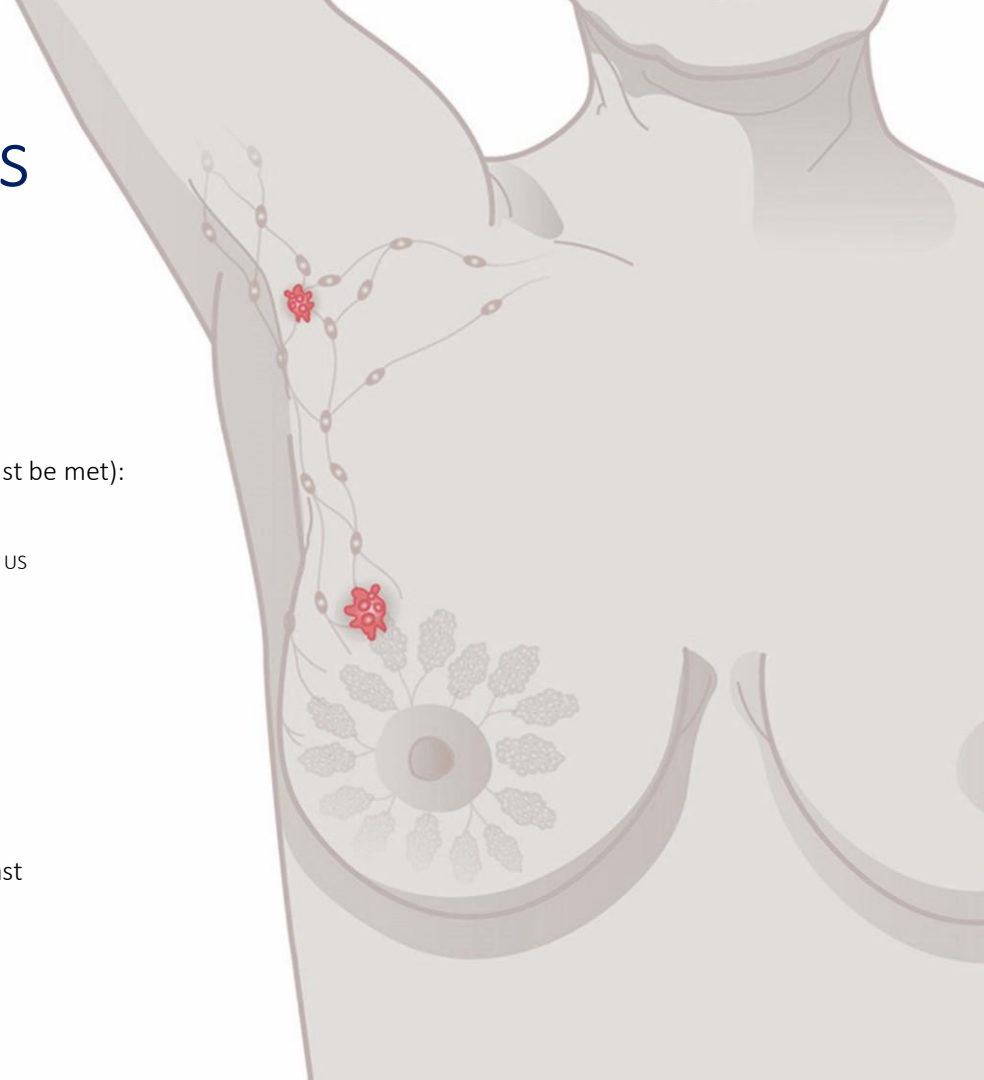
Materials and methods

- Ethically approved German prospective multi-center study (ClinicalTrials.gov ID: NCTNCT03975855).
- Patients with clinically/sonographically suspicious axillary lymph nodes at the time of breast cancer diagnosis underwent minimally invasive lymph node tissue sampling following written informed consent.
- A comprehensive set of risk parameters characterizing the anatomic complexity and procedural difficulty of the biopsy was defined and recorded.
- Initial results based on 115 patients have recently been reported [1]. Post-hoc subgroup analysis presented herein includes 50 patients who presented with at least one major risk parameter.

[1] Thill M, Kühn T, Peisker U, Stachs A, Reinisch M, Malter W, Gruber I, Paepke S, Olse M, Schässburger KU. British Society of Breast Radiology Virtual Annual Scientific Meeting 2021. Breast Cancer Res 23, 98 (2021). https://doi.org/10.1186/s13058-021-01471-2

Materials and methods

- Inclusion criteria
  - cT1-4c (multifocality/multicentricity permitted)
  - Female/male patient age ≥ 18 years
  - cN+ based on the following criteria (at least one criteria must be met):
    - lymph node is palpable
    - cortical asymmetry (focal or diffuse cortical thickening of >3mm) under US
    - cortex: hilum ratio >2:1 under US
    - loss of hilum/cortex structure under US
  - Written informed consent (ICF)
- Exclusion criteria
  - Suspicious lymph nodes after neoadjuvant therapy
  - No confirmed breast cancer and no abnormality in the breast
  - Patient uses Marcumar
  - Pregnant and lactating women

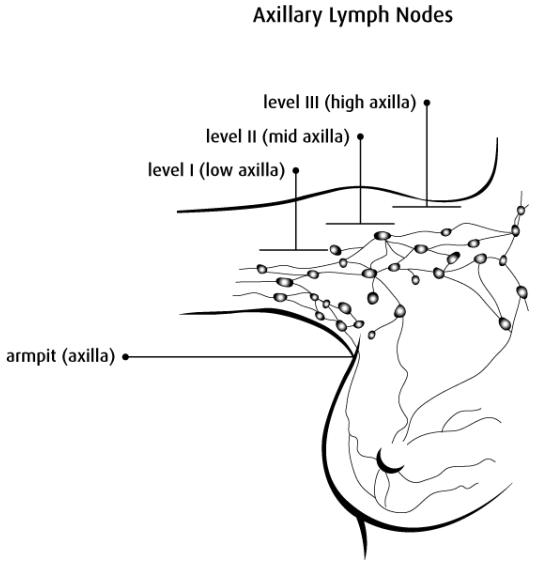


Materials and methods

An expert panel established risk parameters to characterize the anatomic complexity of axillary biopsy procedures.

Major risk parameter
• LN proximity to vessel <5 mm
• LN proximity to muscle <5 mm
• LN proximity to thoracic wall <5 mm
• LN size <10 mm

Minor risk parameters
• LN proximity to vessel 5-10 mm
• LN proximity to muscle 5-10 mm
• LN proximity to thoracic wall 5-10 mm
• LN size 10-15 mm
• Patient presents with prior axillary surgery, e.g. SLNB, axillary dissection, other / other operations, e.g., benign skin tumors, abscess)
• BMI <18.5
• BMI >30
• LN to skin distance <5 mm
• Patient presents with mobility restriction



Materials and methods

- Primary Endpoint
  - Rate of successful biopsies ("success rate")
- Secondary Endpoints
  - Rate of adverse events
  - Rate of patients presenting with risk parameters for an anatomically complex procedure
  - Rate of cases in which pulses facilitated stabilization of the target lesion during needle insertion
  - Rate of cases in which pulses facilitated control during needle insertion
  - Average number of insertions per case
  - Average number of samples per case

Results

- 50 patients presented with <u>at least one major risk factor</u>

# Risk Parameters	# Patients
1	62% (31/50)
2	32%(16/50)
3	6% (3/50)

Major risk parameter*
• LN proximity to vessel <5 mm
• LN proximity to muscle <5 mm
• LN proximity to thoracic wall <5 mm
• LN size <10 mm

- Mean age of the cohort was 58 years
- Mean lymph node size of 15.5 mm

*An expert panel established risk parameters to characterize the anatomic complexity of axillary biopsy procedures

Results

Primary Endpoint

Success rate for tissue sampling from the lymph node was 96 % (48/50).

Secondary Endpoints

- Adverse Events
  - Hematoma in the axilla occurred in 2% (1/50) of patients (mild). Did not require treatment.
  - Pain in the axilla was reported in 4%(2/50) of patients (one mild, one moderate).
- An average of 3 samples were obtained per patient with a mean of 1.5 needle insertions.
- Pulses facilitated control during needle insertion in 94% (47/50) of cases.
- Pulses facilitated stabilization of the target lesion during needle insertion in 92% (46/50) of cases.

Conclusion and outlook

In challenging cases of axillary biopsies the Pulse Biopsy Device shows a high success rate of tissue sampling (96%). In conclusion;

- **Safe and effective:** for tissue sampling in axillary lymph nodes which were categorised as high risk, indicating high anatomic complexity and procedural difficulty.
- **Provides controlled needle insertion**: and the pulses were perceived to stabilize the target lesion.
- **Multiple samples**: obtained with a single insertion.

Available in Europe The Pulse Biopsy System represents the next generation of tissue sampling, providing high needle control and tissue yield. It has recently become commercially available in Europe (for breast and axillary lymph nodes), with different needle options.

14G NeoNavia FlexiPulse probe

Thank you!