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German prospective multi-center study (PULSE): Novel biopsy device is safe and effective in axillary lymph nodes

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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.

Increasing the volume of tissue removed may increase the diagnostic yield and sensitivity for detection of metastatic deposits. Due to the vicinity of the lymph nodes to blood vessels and nerves, it poses challenges and limits the feasibility of currently used biopsy devices.

A 14G open-tip vacuum-assisted needle with pulsed insertion technology (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 and promising first results in the axillary lymph nodes.

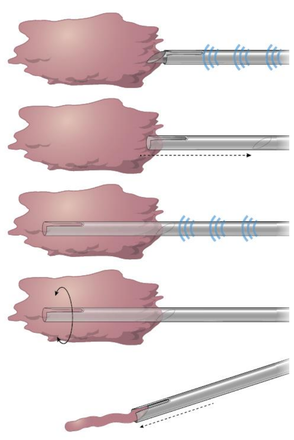
Purpose was to document the performance characteristics of the NeoNavia biopsy device in the axillary lymph nodes and provide basic insights into the complexity of axillary biopsy procedures.

Methods

Ethically approved German prospective multi-center study (ClinicalTrials.gov ID: NCT03975855). 138 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.

Primary endpoint was success rate (i.e., samples obtained from the lymph node). Secondary endpoints included rate of adverse events, rate of patients presenting with risk parameters for an anatomically complex procedure, rate of cases in which pulses facilitated control and stabilization of the target lesion during needle insertion, number of insertions per case and number of obtained samples per case.



1. Pulses are used to advance the needle through healthy tissue towards the lesion.
2. When the needle has reached the lesion, the dissection tip is retracted and the open-tip sampling needle faces the lesion.
3. Pulses are used to advance the sampling needle into the lesion thereby filling it with tissue. Insertion length can be adapted to the lesion at hand.
4. The tissue sample is cut off by a rotation of the sampling needle.
5. The biopsy needle is withdrawn. The tissue sample is ejected by extending the dissection tip into its initial position.

Schematic of the novel open-tip pulsed biopsy device.

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

Inclusion and exclusion criteria of the PULSE study.

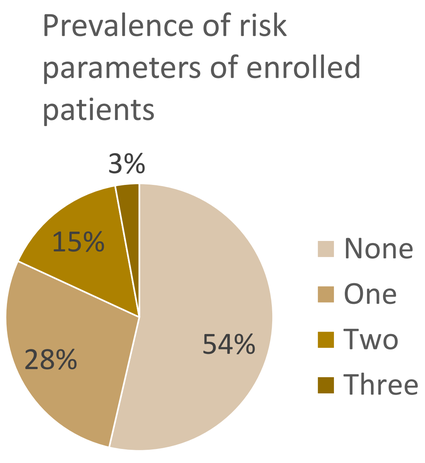
Major risk parameters
Lymph node distance to vessel <5 mm
Lymph node distance muscle <5 mm
Lymph node distance thoracic wall <5 mm
Lymph node size <10 mm

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

Results

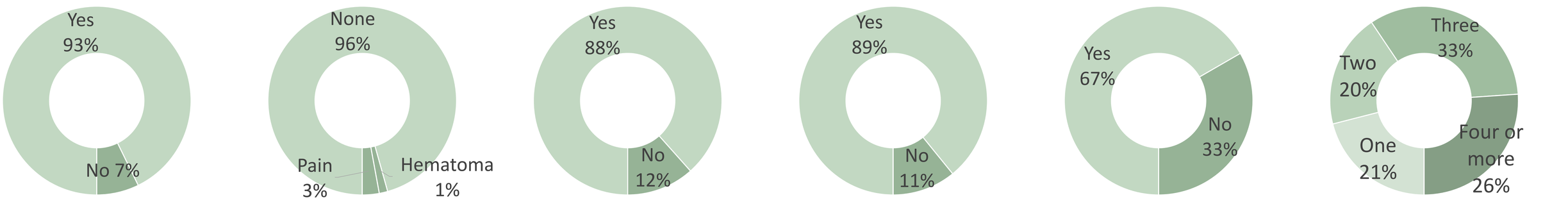
138 patients underwent a biopsy procedure using the novel biopsy device. Mean patient age was 57 years (range 26-86) with a mean primary tumor size under ultrasound of 28 mm (range 7-125) and a mean lymph node size of 18 mm (range 7-46).

46% (64/138) of included patients presented with at least one major risk parameter.



Success rate for a biopsy procedure was 93% (128/138). Pain occurred in 2.9% (4/138) of cases (three of severity mild, one moderate). Hematoma occurred in 1.4% (2/138) of cases (one mild, one moderate).

An open-tip needle design allows for multisampling, i.e., procedures with >1 sample obtained with a single insertion. Multisampling was observed in 67% (92/138) of procedures. In total, a median of 3 samples (range 1-8) were obtained with a median number of 1 insertion (range 1-3).



Conclusion

In conclusion, the device is safe and effective for tissue sampling in axillary lymph nodes. The study enrolled a well-documented and wide-ranging patient cohort regarding presence of pre-defined risk parameters characterizing the anatomic complexity and procedural difficulty of the procedure.

Pulses were perceived to provide control during needle insertion as well as stabilization of the target lesion. It was possible to obtain multiple samples with a single needle insertion.

The technologies evaluated herein have since been implemented into the FlexiPulse Probe of the NeoNavia Biopsy System (NeoDynamics, Sweden), a pulse biopsy platform enabling several needle options.

Newly developed biopsy platform incorporating novel needle design.

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