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Diagnosis of axillary metastatic disease using micro-pulse biopsy system - current status and future developments

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Background

The basis for systemic and surgical treatment decision making is a reliable assessment of axillary lymph node status. The development of axillary diagnostics moves into the direction of non-surgical, minimally-invasive procedures.

Tissue sampling and clip-marking of radiologically metastatic and suspicious lymph nodes (iN+) in the context of conversion to yiN- is limited in certain situations by the size and location of individual lymph nodes. Automatic or semi-automatic spring-loaded biopsy systems are currently being used for tissue sampling.

Recently a new micro-pulse biopsy system has been developed (NeoNavia Biopsy System, NeoDynamics, Sweden) that features a technology for controllable and precise needle insertion and a 14G vacuum-assisted open-tip needle for maximum tissue yield (see fig 1).

Pre-clinical tests have shown tissue yields around 3-4x higher compared to 14G CNB [1] and first clinical results indicate increased precision of “technically difficult lesions, including deep axillary lymph nodes [2].

1. The system features an open-tip sampling needle and a retractable dissection tip. 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. Vacuum suction assists in increasing sampling yield.
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 The biopsy needle is withdrawn.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.

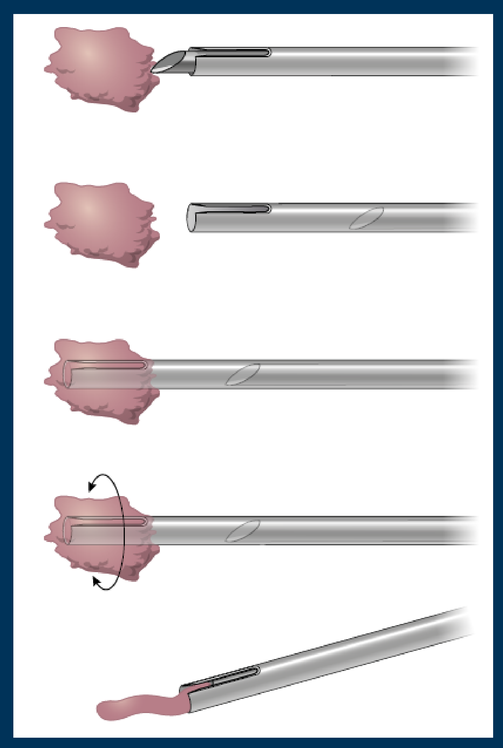

Fig. 1: Biopsy methodology of novel micro-pulse biopsy system.

Methodology

The technology (see fig.2) is currently systematically evaluated In a German multi-centre registry trial of the AG Mimi (PULSE, ClinicalTrials.gov ID: NCT03975855)

Sonographic characteristics of the lymph node as well as factors indicating a challenging procedure (e.g. vicinity to blood vessel or thoracic wall, size of the lymph node) are systematically assessed and analyzed (see tab. 1&2). The goals is to enrol a total of 140 patients with 26 recruited as of June 2019.

<u>cN+ based on the following criteria (at least one criteria must be met):</u>
- olymph node is palpable
- ocortical asymmetry (focal or diffuse cortical thickening of >3mm) under US
- ocortex:hilum ratio >2:1 under US
- loss of hilum/cortex structure under US

Tab.1: Criteria for suspicious lymph node applied in the PULSE trial.

Fig. 2: Images of NeoNavia biopsy system evaluated in the PULSE trial

<u>Major risk parameter</u>
- LN proximity to vessel <5 mm
- LN proximity to muscle <5 mm
- LN proximity to thoracic wall <5 mm
- LN size <10 mm

<u>Minor risk parameters</u>
- 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

Tab. 2: Parameters established by an expert panel to characterize the anatomic complexity of axillary biopsy procedures.

Results & Outlook

Newly developed biopsy modalities could improve diagnostic accuracy of minimally-invasive diagnostics in the axilla.

The biopsy method of an ultrasound-guided pulsed needle insertion has been pioneered in the NeoNavia biopsy system. Paired with a novel needle design, this biopsy procedure is now being assessed in clinical practice with a focus on axillary diagnosis.

Practical clinical experience is used to further develop the system to optimize handling and implement the micro-pulse biopsy method as a multimodal platform technology.

By adding additional needle types (i.e. CNB and VAB sampling needles) to the micro-pulse biopsy platform (see fig. 3), NeoNavia has the potential to replace conventional ultrasound-guided biopsy methods used in the breast and axilla, potentially improving diagnostic accuracy and decreasing overall costs.

Fig. 3: Images of next generation NeoNavia biopsy system featuring three different needle types.

References

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yield tissue acquisition. Physica Medica. 2018;46:25-31.
[2] British Society of Breast Radiology Annual Scientific Meeting 2017. Breast Cancer Research 2017, 19(1):116