A Novel Biopsy Device for Ultrasound-Guided Tissue Sampling Evaluated in the Axillary Lymph Nodes: A Prospective, Multi-Center Study (PULSE)

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Presenter(s)

Marc Thill, MD, PhD

Professor
Agaplesion Markus Hospital

Purpose: For biopsy procedures that are complex and difficult due to challenging anatomical locations, e.g., biopsies of lymph nodes in the axilla, ultrasound-guided biopsies with regular core needles (CNB) or vacuum needles (VAB) have some inherent drawbacks related to needle control, tissue yield, and tissue trauma. With the goal of avoiding these drawbacks, a novel 14G vacuum-assisted open-tip biopsy needle was recently developed. This needle uses pneumatic pulse technology in order to provide a controlled needle insertion and precise lesion targeting (NeoNavia Biopsy System, NeoDynamics AB, Sweden). Purpose of the PULSE study (NCT03975855) was to document the performance of this novel device in the axillary lymph nodes.

Materials and Methods: In this ethically approved German prospective multi-center study, 138 patients with clinically/sonographically suspicious axillary lymph nodes at the time of breast cancer diagnosis underwent ultrasound-guided lymph node biopsy using NeoNavia following written informed consent. A broad set of risk parameters that identified the anatomic complexity and procedural difficulty of the biopsies were defined and recorded. Primary endpoint was success rate (i.e., biopsies from the lymph node).

Results: Mean age of the cohort was 56.8 years with a mean lymph node size of 17.8 mm. 46% (64/138) of patients presented with at least one of four major risk parameters (lymph node diameter <10mm, proximity to blood vessel/muscle/thoracic wall <5mm). Success rate for biopsies from the lymph node was 93 % (128/138). Hematoma in the axilla occurred in 1.4% (2/138) of patients (one mild, one moderate). Pain in the axilla was reported in 2.9 % (4/138) of patients (three mild, one moderate). None of these complications required treatment. On average, 2.82 samples were collected from each patient with a mean of 1.36 needle insertions. In 67% (92/138) of patients, more than one sample per single insertion was obtained by the operator. The pneumatic pulses promoted control during needle insertion in 89% (123/138) and stabilization of target lesion during needle insertion in 88% (122/138) of patients.

Conclusion: The biopsy device proved safe and efficacious for ultra-sound guided biopsies in the axillary lymph nodes. Pneumatic pulses promoted needle control and stabilization of target lesions during insertion of the needle. It was possible to obtain multiple samples with a single insertion.

Clinical Relevance Statement: A new pulse biopsy technology designed for controlled needle insertion, accurate lesion targeting, and high tissue yield has been developed with documented success in percutaneous axillary lymph node biopsies.

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