Tools for precision medicine: Novel open-tip pulsed biopsy needle used to monitor neoadjuvant treatment response

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2021 Disclosures

- None

Goals and Objectives

- To evaluate breast biopsy procedures with a new biopsy system (NeoNavia®, NeoDynamics, Sweden) in approximately 20 women with a suspected breast cancer lesion at Karolinska University Hospital, Stockholm, Sweden.

Background

- Breast cancer screening programs have been implemented on a large scale in several developed countries in order to achieve an early diagnosis
- A timely and correct diagnosis of the disease remains crucial for personalized treatment planning and patient outcome
- It is generally accepted that the final diagnosis of radiologically malignant suspicious lesion (BI-RADS 4 or 5) has to be confirmed using percutaneous biopsy techniques

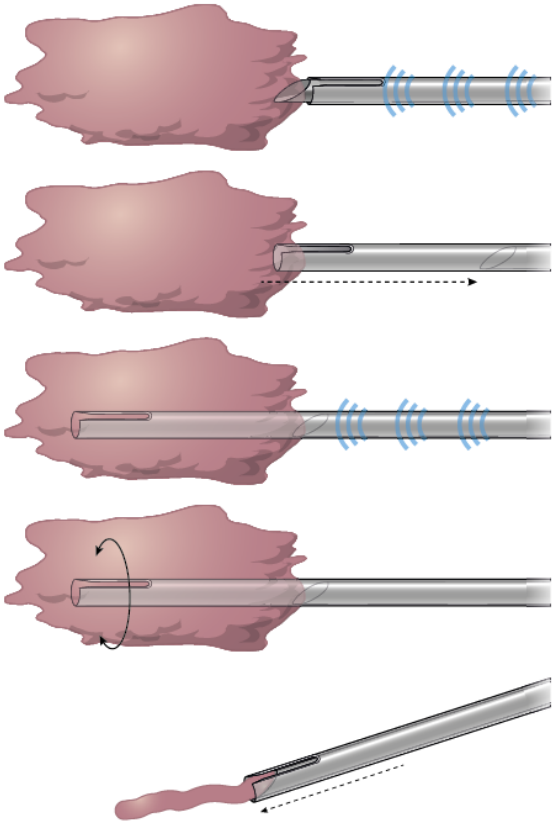
Background cont’d

- The requirement of the biopsy device is to deliver tissue samples that enable a histopathologic analysis
- The primary goal of the initial biopsy of any abnormality is to diagnose the breast lesion as benign or malignant
- The sharp, solid tip of standard biopsy devices used today has a length of 5-15 mm, and when sampling small tumors the needle tip complicates targeting the lesion
- The sharp needle tip may completely penetrate the lesion and cause trauma, and potentially risk the dissemination of tumor cells beyond the original extent of the tumor

Background cont’d

- Avoiding the need for a sharp tip, one of the three needles in the NeoNavia® biopsy system is a 14G open-tip sampling needle with a sampling chamber length of 30 mm (FlexiPulse™)
- The biopsy system incorporates pulse technology for a precise and controlled penetration of any tissue, allowing the physician to navigate the 14G open-tip sampling needle with millimeter-like precision
- The pulses can be used to increase precision and penetrate challenging tissue, e.g. dense breast tissue with ease
- For tissue sampling, pulses are used to advance the sampling needle into the lesion until the desired amount of tissue has entered the needle

NeoNavia® sampling technique with FlexiPulse™



1. *The FlexiPulse probe 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.*

Purpose

- To evaluate breast biopsy procedures with a new biopsy system in 20 female patients with suspicious breast lesions, and to retrospectively analyze the trauma after the biopsies were collected. The results of histopathology, patient comfort, bleeding, hematoma formation and device deficiencies were to be evaluated.

Methods

- This was a retrospective, single center, observational study to evaluate breast biopsy procedures using the NeoNavia® biopsy system.
- Prospective documentation of procedure related variables.
- Ethically approved retrospective analysis of patient data.

Methods cont’d

- Approximately 20 female’s ≥ 18 years with a suspected breast cancer tumor were invited to participate in this study.
- The NeoNavia® biopsy system was used for breast biopsy in accordance with clinical routine and current clinical guidelines.
- The data reported in the CRF were derived from source documents and monitored by the monitor.

Results

- 20 patients underwent a biopsy using NeoNavia® biopsy system with 19 cases available for analysis. Patient median [range] age was 53 [32-80] years. Tumors had a median [range] diameter of 30 [20-80] mm.
- Out of 56 samples obtained; 100% (56/56) were judged by the investigator as “very good”.
- Pulses aided tissue penetration and increased precision of lesion targeting.

Results cont’d

- One patient reported slight pain, possibly due to insufficient local anesthesia.
- No post-procedure complications were noted during the study.
- In four cases the operator judged single samples obtained by NeoNavia® equivalent to 3-5 CNB samples, which allowed for NeoNavia® samples to be divided accordingly.

Conclusion

- The biopsy method is well suited for tissue sampling of extensive areas such as for repeat biopsies in the neoadjuvant setting or scattered micro calcifications. Obtaining an elongated full-core sample equivalent to multiple CNB samples could spare the patient repeated needle insertions and decrease procedure time. Clinical experience is used to improve the system and implement the pulse biopsy method in a multimodal biopsy platform.