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Using Confocal Endomicroscopy for Digital Biopsy During Brain Surgery: Presentation of a Study Protocol

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1. Introduction

Digital technologies are considered to be an essential stimulus for new developments in medicine. Telemedicine, remote diagnosis or therapy using information and communication technologies, is especially promising [1].

Brain tumor surgery is a complex medical procedure and requires the involvement of several specialties. During surgery, the neuro-surgeon needs to regularly check the borderline between healthy and cancerous tissue to ensure complete resection of the tumor, which is vital for postoperative patient survival. To definitely confirm tissue status, instantaneous sections, the extraction of a tissue sample, is performed during surgery [2]. The biopsy is then evaluated by a pathologist. Currently, the sample must be sent to the pathologists for diagnosis and the results are transferred back to the surgery via telephone. This process is problematic as it takes a long time and requires extensive human resources. In consequence, the results often arrive too late for the surgeon to base decisions on them and to adjust the procedure if necessary. Digitizing the process could shorten the assessment time and improve patient outcomes.

2. Study protocol: Improving the Process of biopsy during brain tumor surgery

2.1. Study design and process

An interventional pilot study testing the image output tool CONVIVO of the Zeiss company at the Department of Neuropathology of the Technical University of Munich

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University Hospital will be conducted. CONVIVO allows in vivo cellular imaging of the surgical site. In combination with a contrast agent, the confocal microscope can visualize cellular tissue structures in real-time during surgery. Digital images can be remotely analyzed by a pathologist. Contrary to the current process, tissue removal is no longer necessary and the results are available shortly after [3,4]. For this study, the pathology department will be digitally connected to the operating room and CONVIVO. The selection of an available pathologist within the clinic will be automated. The study will consist of five work packages distributed across 36 months:

1. Literature review and expert interviews to identify potential business models.
2. BPMN-modelling and evaluation of the business processes identified in step 1.
3. Cyclical development and implementation of the pilot system (PLAN, DO, CHECK, ACT). Adequate staff training is of particular importance.
4. Evaluation of the system in light of the study aims.
5. Development of an action plan with short, middle and long-term measures to ensure continuity and a broader implementation.

2.2. Study aims

The study aims to assess the use of the digital biopsy tool CONVIVO during brain surgery. In particular, the study intents to evaluate the following indicators to measure the tool's success: Economic feasibility, usability, data reliability and medical outcome.

2.3. Ethics

Patient data will only be stored and transferred within the secure hospital network. All study data will be anonymized and aggregated. The results of the study will be published and primary data made publicly available.

3. Conclusion

Digital biopsy has the potential to not only streamline the clinical processes during brain surgery but also improve medical outcomes and patient survival by eliminating the necessity to remove tissue for analysis and increasing the likelihood of complete tumor resection. The test and evaluation of the tool will help to confirm this hypothesis.

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