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Safety of a new “all in one” 3D device for fiducial tumor marking: A pilot animal study

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Abstract

INTRODUCTION: Malignant lung lesions are commonly treated with stereotactic body radiotherapy e.g. Cyberknife®. However, a common problem of existing markers is migration which requires placement of several devices (usually 3). The purpose of the study was to demonstrate feasibility of a new « All in 1 » shape memory (Novatech®) markers, with safety and efficacy as key points, in a porcine model.

METHODS: 55 devices with 3 different shapes were inserted in 8 Piétrain pigs, using flexible bronchoscopy under general anesthesia. Follow-up period: 4 weeks with CT scans analysis. The markers where launched in different peripheral sub-segments using a guide sheath under fluoroscopy control. Evaluation: Procedure time, ease of placement, blinded CT scan analyses for evaluation of migration, complications and histological analysis.

RESULTS: All 55 devices were easily inserted into the peripheral bronchi and visualized under fluoroscopy. The average procedure time was 5 min (+/- 2,6). During the 4 weeks clinical follow up and CT evaluation, no immediate or late complication occurred (pneumothorax, pneumonia, severe granulations or bleedings). Migration has been avoided by changing the design. The pathological investigations performed in the explanted lungs, at one month did not led to drastic alterations of the bronchio-alveolar structures at the site of implantation or distally.

CONCLUSIONS: In this pilot animal study the new « all in 1 » device for fiducial tumor marking was easy, quick and safe to use. It could be demonstrated that migration risk can be reduced with the right design and the lung

functioning were not substantially affected by the device implantation.

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