Better Effectiveness and Efficiency by Measuring and Modelling Interventional Therapies

DELIVERABLE D4.3.2
State of the art on Real-time devices and navigation

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V0.1	May 24, 2017	Starting version, from template
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Deliverable review procedure:

- **4 weeks before due date**: deliverable owner sends deliverable –approved by WP leader– to Project Manager.
- **Upfront** PM assigns a co-reviewer from the PMT group to cross check the deliverable
- **2 weeks before due date**: co-reviewer provides input to deliverable owner
- **Due date:** deliverable owner sends the final version of the deliverable to PM and co-reviewer

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1 Introduction

The goal of this document is to provide a state-of-the-art review on **real-time devices and navigation** that enable the CT-guided Percutaneous Needle Positioning procedure. This is limited to the time the patient is on the intervention table, so that adaptations to the treatment plan can be made if intervention results are sub-optimal. The objective is to identify how patient risk can be minimized and intra-interventional imaging and other tools can be deployed to better treat patients with respect to the wide range of intervention tools and options.

The results are based on open literature and the knowledge provided by the technical and clinical partners of the project.

2 Executive summary

This document is a part of the “State of the Art” descriptions of the interventional procedures that are targeted / used by the BENEFIT project. The goal of BENEFIT is to develop technologies that improve efficiency and effectiveness of minimally invasive interventional procedures based on improved quantification and modeling before, during and after interventions, whereby imaging is used as one of the major tools.

In this deliverable, the CT-guided Percutaneous Needle Positioning is addressed. From a clinical perspective these procedures are within the domain of oncology.

This deliverable D4.3.2 summarizes the state of the art for these Needle Positioning interventions and describes a clinical trial for evaluation of a novel needle positioning system which is currently in progress. Also references to overview articles on percutaneous procedures are given.

3 Glossary

CT: Computer Tomography: diagnostic imaging method to mathematically reconstruct 3D images from a rotational sequence of 2D X-ray slices

Percutaneous: Literally “through the skin”: interventional approach to diagnose or treat a (suspected) lesion with a tool (like a catheter or needle) which has been inserted via a small opening in the skin instead of open surgery

4 Real-time Devices

This is by no means an exhaustive study of all real-time devices used in and around intra-interventional imaging. The selection made here is focused on the techniques used in BENEFIT, and especially in the Use Case of liver oncology as defined in the project. However references are given to documents with a more extensive overview.

4.1 CT-guided Percutaneous Needle Positioning

4.1.1 Introduction

Over the last few years, advances in technology are accelerating the transition from open surgery to minimally invasive and image-guided interventional procedures. In the field of oncology, percutaneous approaches for diagnostic and therapeutic interventions have emerged and matured. [Arnolli 2015] [Donadon 2016] [Sag 2016] The current workflow for image-guided percutaneous techniques is based on a freehand approach. The physician estimates the position of the lesion and the required needle insertion depth and orientation to reach the predefined target. Often, adjustments of insertion angle are needed to minimize the error of the needle tip with respect to the planned target, which leads to an iterative process of estimating, manually (re)positioning the needle and CT scanning to verify the adequacy of the needle tip position. (Arnolli 2015) Erroneous angle estimations and needle insertions unnecessarily increase tissue damage, patient exposure to X-rays due to repetitive CT scanning, and thus procedural time and costs. [Arnolli 2015] [Kettenbach 2015]

The objective of the BENEFIT project encompasses the design and development of a system which improves the efficiency and effectiveness of CT-guided percutaneous needle positioning in the thorax and abdomen.

4.1.2 Technical State of the Art

With the goal of facilitating and improving image-guided percutaneous interventions by means of needle guidance and positioning, a broad range of devices have been developed worldwide, varying from passive aids to fully automated robotic systems. [Arnolli 2015] [Kettenbach 2015] However, the number of systems that are clinically accepted and adopted is limited. [Arnolli 2015] [Kettenbach 2015] DEMCON has developed a needle positioning system (NPS) to aid the physician in efficiently and effectively placing the needle tip at the predefined target, while focusing on minimal interference of the workflow and clinical acceptance.

Figure 1: the DEMCON needle positioning system (image courtesy DEMCON)

4.1.3 Usage in intervention and treatment evaluation

Since February 2017, an open randomized controlled study is being performed at the University Medical Center Groningen to investigate the number of needle repositions to reach an adequate target position, comparing the conventional freehand approach to the navigation guided approach for CT-guided percutaneous ablation of hepatic tumors. The study population consists of patients eligible for CT-guided percutaneous ablation of liver tumor(s), randomizing 42 tumors in total.

The workflow for both approaches is largely the same. All procedures are carried out in the interventional CT room. After inducing general anesthesia, the patient is positioned on the CT table. The area of needle insertion is estimated based on pre-operative imaging and a radiopaque grid is placed within this region as reference. A contrast-enhanced multi-phase CT-scan is made to visualize the region of interest. The physician identifies the lesion and selects the needle target position. Then the needle path and entry point on the skin are planned such that the needle will not coincide with critical and impenetrable structures, such as large blood vessels and bones. A laser, which is incorporated in the CT gantry, is used to project a line that coincides with the plane of the planned entry point. The position of the entry point is then retrieved at the intersection of the laser line with the grid.

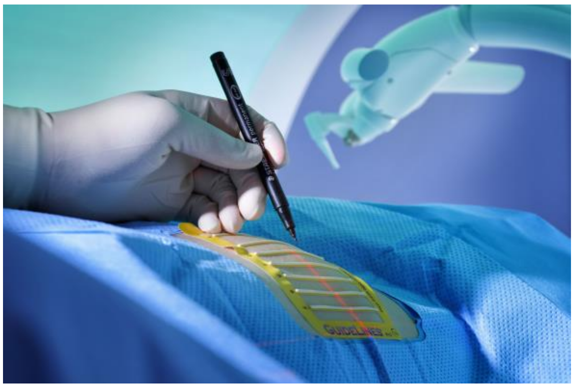

Figure 2: Retrieval of the entry point (image courtesy DEMCON)

If the freehand approach is used, the physician then translates the planned path to the patient and estimates the required insertion depth and needle orientation to reach the predefined target. A CT-scan is made to visualize the needle path and position of the tip, iteratively adjusting the insertion depth and angle and CT-scanning to verify whether the distance of the needle tip with respect to the planned target is sufficiently minimized. Between one and six needle repositions are normally needed to reach an adequate position of the needle tip, which is often still not optimal.

During the guided approach, the system is placed onto a rail that is mounted to the CT-table. The process of patient preparation, path planning and entry point retrieval is the same as for the freehand approach. Subsequently, the physician manually positions the operating platform such that the remote center of rotation of the needle guide coincides with the retrieved entry point. Pressing one of the push-buttons automatically initiates the locking system. A new CT-scan of the anatomical region of interest together with the needle positioning system is made. Using these scans, the target and planned path are displayed for review and the position and orientation of the system with respect to the target are determined. The required insertion depth and angles are calculated and after the physician's approval, the needle guide automatically aligns in the according orientation. The physician manually inserts the needle at the calculated depth and a control CT-scan is made to verify the location of the needle tip.

Up to date, a total of 35 tumors have been included in the clinical trial. After completion of the clinical study, the results will be analyzed and published in a peer-reviewed journal.

Figure 3: Left: positioning the NPS. Right: manual needle insertion (image courtesy DEMCON)

5 Bibliography

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