Intra-operative navigation of a 3-dimensional needle localization system for precision of irreversible electroporation needles in locally advanced pancreatic cancer

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Abstract

Introduction: Irreversible electroporation (IRE) uses multiple needles and a series of electrical pulses to create pores in cell membranes and cause cell apoptosis. One of the demands of IRE is the precise needle spacing required. Two-dimensional intraoperative ultrasound (2-D iUS) is currently used to measure inter-needle distances but requires significant expertise. This study evaluates the potential of three-dimensional (3-D) image guidance for placing IRE needles and calculating needle spacing.

Patients and methods: A prospective clinical evaluation of a 3-D needle localization system (Explorer™) was evaluated in consecutive patients from April 2012 through June 2013 for unresectable pancreatic adenocarcinoma. 3-D reconstructions of patients' anatomy were generated from preoperative CT images, which were aligned to the intraoperative space.

Results: Thirty consecutive patients with locally advanced pancreatic cancer were treated with IRE. The needle localization system setup added an average of 6.5 min to each procedure. The 3-D needle localization system increased surgeon confidence and ultimately reduced needle placement time.

Conclusion: IRE treatment efficacy is highly dependent on accurate needle spacing. The needle localization system evaluated in this study aims to mitigate these issues by providing the surgeon with additional visualization and data in 3-D. The Explorer™ system provides valuable guidance information and inter-needle distance calculations.

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Introduction

Irreversible electroporation (IRE) is a nonthermal, focal ablation technique that has shown tremendous promise as an effective cancer therapy. Reversible electroporation has long been used as a technique for electotransfection of genetic material or intracellular drug delivery.[1] When the energy of the pulses is increased above a certain electric field threshold, the permeabilization becomes irreversible resulting in apoptosis. The safety and efficacy of IRE has been demonstrated in multiple animal models.[2–4] Similarly, early efficacy and safety has been demonstrated in the use of IRE in the treatment of locally advanced pancreatic cancer (LAPC).[5,6] However, significant hurdles and limitations remain with the use of IRE not just in LAPC, but in other locally advanced soft tissues. The two most challenging hurdles are the requirement of placing multiple needles (commonly 4) in a bracketing fashion in perfect parallel and with precise spacing (no closer than 1.5 cm and no farther than 2.3 cm apart). These two technical challenges have been responsible for incomplete IRE, local failures, and local recurrences.[7–9]

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These two hurdles—i.e., image accuracy of needle placement and needle spacing—could be addressed with the advent of with real-time intraoperative image-guided surgery (IGS).[10−13] Most IGS has been performed and published within hepatic resection and hepatic ablations. IGS has been utilized in pancreatic surgery; however, no one has utilized this technology for pancreatic ablations. The requirement of any type of IGS system is to utilize high quality preoperative medical images that are appropriate for slice thickness and contrast timing, which are then registered during the operation with 4 intraoperative landmarks (e.g., portal vein, biliary bifurcation, etc.). These landmarks must be distinct and the location accurate in order to provide a 3-D image of the organ of interest. Certain IGS systems allow for the interactive use of the preoperative images to enhance ultrasound localization and targeting.

Thus the aim of this study was to evaluate the use of one of the commercially available IGS units intraoperatively. The goal of this study was to evaluate the feasibility of this intraoperative navigation system and assess if it provided clinically valuable information in the guidance of precise placement of IRE ablation needles.

Patients and methods

The study protocol was approved by the University of Louisville Institutional Review Board, and all patients were provided with written, informed consent forms. Our study consisted of a prospective clinical evaluation of 3-D needle localization using a 3-D intraoperative navigation system. This was evaluated in 30 consecutive patients with unresectable pancreatic adenocarcinoma who underwent IRE from April 2012 through June 2013. Data was compared to that of patients treated without the use of 3-D localization. The electroporation system we used was the Angiodynamics NanoKnife irreversible electroporation system (IRE). Preoperative thin-cut, 3-phase, multislice CT scans (pancreas protocol) were obtained as part of the workup and staging protocol in patients with a planned IRE procedure.

Localization and visualization of the pancreas via the 3-D intraoperative navigation system utilizes preoperative imaging with acquired data corresponding to the geometry and anatomy of the area in question. The 3-D image of the patient's anatomy is then matched with the actual anatomy. The user then identifies tumors and adjacent anatomy on the preoperative scan and their locations are inserted into the 3-D model using the Pathfinder planning software (Scout™ (Pathfinder Technologies, Nashville, TN)). The processed begins with first obtaining a high quality (defined as thin cut <2 mm triphasic non-contrast, arterial phase, and venous phase) pancreatic protocol CT scan for appropriate staging and tumor localization (Fig. 1). The DICOM images are then uploaded into a either mobile (Laptop version of Scout™) or integrated version of Scout™, where the 3-D reconstruction is performed after identifying key structures (i.e. SMA, SMV, Port Vein, Pancreatic Duct, Pancreatic tumor itself, etc…) Critical to the optimization of this 3-D structure is the quality of the CT scan. The 3-D processed images are then reviewed for clinical accuracy prior to the operation. Once confirmed these processed images are uploaded into a commercially available navigation system (Explorer™, Pathfinder Technologies, Inc., Nashville TN) that is the working system in the OR. Intraoperative surface and anatomical features at different anterior-posterior and cranial-caudal depths (at least 4 to 5) are acquired by manually touching the regions/organ of interest in the patient using an optically tracked probe (Fig. 1) and mark it on the 3-D reconstructed image to establish accurate orientation. Once the desired anatomical features are identified by the user, the Explorer™ device then registers the image for intraoperative use by the surgeon.

The registration accuracy is then calculated an confirmed while using a optically tracked Ultrasound probe and a optically tracked IRE needle. Once these were confirmed to be within 10−12 mm or less of target structures, needle placement was then begun. The IRE needles we placed using both the navigation and US simultaneously.

Inter-needle measurements were taken via intraoperative ultrasound (iUS), which is considered the standard, and compared to the measurement obtained using the Explorer 3-D navigation system. At the completion of each case the surgeon filled out a questionnaire related to the use of the navigation system.

Literature review

A literature review was completed after electronic searches were performed using PubMed and EMBASE electronic databases. The search was restricted to studies in English using a human model. The keywords used to search the database were navigation, pancreas/pancreatic, intraoperative and augmented reality. The references used in the studies that were identified were also reviewed.

To be included, studies had to be specifically about navigation surgery techniques involving the pancreas. Additionally, studies had to be from within the past seven years and contain data about patients involved in the study. Duplicate articles were excluded.

The full text articles that met criteria were reviewed, with a focus on the type of navigation system and how it was used intraoperatively, the outcomes noted in each study and the limitations and conclusions found in each study. These points of interest were compiled in a table for simple and quick comparison between articles.

A quality assessment of each article was performed using the Newcastle−Ottawa scale.[14] A score from 0 to 9 is given to the articles based on the selection, comparability and outcome of group(s) involved in the study. A higher