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Real-Time CT–Guided Percutaneous Placement of LV Pacing Leads

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OBJECTIVES The aim of this study was to assess the feasibility of real-time computed tomographic (CT) imaging to guide the percutaneous placement of left ventricular (LV) leads in an animal model.

BACKGROUND Cardiac resynchronization therapy has been shown to improve morbidity and mortality in patients with chronic heart failure. However, placement of the coronary sinus lead can be challenging and may require a more aggressive surgical approach.

METHODS Nine swine were placed in a real-time CT scanner to define the safest percutaneous access strategy. Under real-time CT guidance, a 3.5-F pacing lead was placed percutaneously in the anterolateral LV epicardium (n = 6 swine) or to the posterolateral wall after the creation of intentional left pneumothorax (n = 3 swine) in a tangential (n = 12) or perpendicular (n = 1) approach. Pacing parameters and CT images were assessed during 30-min follow-up. Necropsy findings were compared with real-time CT images.

RESULTS CT imaging successfully defined the safest percutaneous access route in all 13 lead placements and guided the therapeutic creation of pneumothoraces. Needle trajectory remained within 5 mm of the access route defined on CT imaging. LV lead placement under CT guidance was successful in all attempts within 19 ± 7 min. The mean pacing thresholds was 2.5 ± 1.5 V, the mean R wave amplitude was 11.2 ± 5.6 mV, and the mean impedance was 686 ± 103 Ω and remained unchanged after tangential placement during 30-min follow-up. Although no cardiac complications were observed with tangential lead placement (12 of 12), the perpendicular approach resulted in a pericardial effusion requiring pericardiocentesis. At necropsy, CT images correlated well with the in situ pathological results.

CONCLUSIONS Percutaneous placement of LV pacing leads under CT guidance is feasible and might offer an alternative to more invasive surgical approaches in patients with complicated coronary sinus lead placement. (J Am Coll Cardiol Img 2013;6:96–104) © 2013 by the American College of Cardiology Foundation

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Cardiac resynchronization therapy using biventricular pacing has been shown to decrease morbidity and mortality in patients with ejection fractions <35%, QRS-durations ≥120 ms, and New York Heart Association (NYHA) class III or IV symptoms (1–3) and even NYHA class I or II symptoms (4). However, cardiac resynchronization therapy fails to provide significant benefit in a substantial minority (20% to 50%) (5). The placement of a left ventricular (LV) pacing lead via the coronary sinus (CS) fails in up to 10% because of unsuitable anatomy or difficult lead delivery (6). Additionally, it limits potential pacing locations to the areas with accessible CS branches. Areas of myocardial scar, diaphragmatic stimulation, and high pacing thresholds further restrict acceptable lead locations. Consequently, pacing from areas with the best clinical results might not be attainable (7,8). Although surgical epicardial lead placement is frequently performed, this approach is associated with higher morbidity and complication rate.

Real-time percutaneous LV lead placement under computed tomographic (CT) guidance could potentially overcome these limitations, as it has demonstrated excellent accuracy and decreased procedure times in radiological procedures (9).

METHODS

Animal preparation. Nine swine (weight 35 to 40 kg) were injected with 10 mg ketamine intramuscularly, intubated, and maintained on 1% to 2% isoflurane gas (Narkomed, Dragar, Telford, Pennsylvania). End-tidal carbon dioxide and electrocardiography were monitored throughout. Vascular access was obtained by percutaneous puncture of the right femoral vein. All protocols were reviewed and approved by the Animal Care and Use Committee and conformed to the guidelines published in the "Position of the American Heart Association on Research Animal Use."

Image-guided LV lead placement. The animals were brought to a CT scanner with real-time fluoroscopic capabilities (either a Siemens Somatom Plus4 [Siemens Healthcare, Erlangen Germany], a GE LightSpeed RT 16 [GE Healthcare, Milwaukee, WI], or a Philips Brilliance 64 [Philips Medical Systems, Andover, MA]). A contrast-enhanced scout image (60 ml Omnipaque 300 [GE Healthcare], injection rate 2 ml/s) was used to delineate the myocardium, identify LV lead target sites, and evaluate percutaneous access. A second contrast injection (60 ml Omnipaque 300) was performed in 3 animals after LV lead placement. LV lead placement was performed in the first 6 animals with fully inflated lungs to the most lateral LV site, which was percutaneously accessible. In 3 swine, an intentional left-sided pneumothorax was created after selective intubation of the right bronchus. In those animals, the posterolateral target site was arbitrarily defined as a 5-o'clock location of the LV myocardium in a short-axis view. A 20-gauge needle was advanced under real-time CT guidance from a left intercostal position into the pleural space and room air injected until the lateral LV free wall.

After delineation of a safe access route, a 17-gauge spinal needle was advanced percutaneously across the chest wall toward the epicardium. The real-time imaging plane was chosen parallel to the interventional plane to allow full visualization of the needle. Needle navigation was performed under real-time CT guidance along the pre-determined access route. The maximal distance of projected access route (Fig. 1A) and the actual needle tip position during access (Fig. 1B) were measured on the 2-dimensional navigation images to assess the accuracy of needle navigation.

CT imaging was performed using a single-scan acquisition or "point-and-shoot mode" to freeze the cardiac motion (tube voltage 120 kV, tube current 120 to 200 mA, slice thickness 10 mm, spatial resolution 0.5 mm^3, latency 750 to 1,000 ms) and continuous fluoroscopy mode (tube voltage 120 kV, tube current 50 mA, slice thickness 5 to 10 mm, temporal resolution 6 to 8 frames/s), which was displayed inside or outside of the procedure room. After the needle tip was visualized at the epicardial border, a 3.5-F pacing lead (Medtronic, Inc., Minneapolis, Minnesota) was advanced to the needle tip. Electrical signals were recorded with a Medtronic interrogator (Analysis Mode) at a paper speed of 25 mm/s. Potential perforation was assessed with attempts to aspirate blood. Under real-time CT guidance, the needle was advanced tangentially about 10 mm into the myocardium. Once an intramyocardial position had been obtained as assessed by CT imaging, repeat electrical ventricular electrograms were recorded, and the inability to aspirate blood was confirmed. The 3.5-F pacemaker lead was advanced into the myocardium and its helix deployed with 3 to 5 clockwise torquing motions. Acute R wave, lead impedance, and pacing threshold were recorded. The percutaneous

ABBREVIATIONS AND ACRONYMS

CS = coronary sinus
CT = computed tomographic
DLP = dose-length product
LV = left ventricular
NYHA = New York Heart Association

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Figure 1. Real-Time CT Imaging–Guided LV Lead Placement

Right ventricle and left ventricle as well as myocardium seen in contrast-enhanced computed tomographic (CT) image. Projected trajectory for left ventricular (LV) lead indicated by orange line **(A)**. Percutaneous needle **(black arrow)** with tip **(white arrow)** advanced into the myocardium **(B)**. Implanted pacemaker lead seen in midmyocardial position **(white arrows, C)**. CT images correlate well with left parasternal access site **(black arrow, D)** and anterolateral epicardial entry location **(white arrow, E)**. Angulated, tangential placement of lead tip seen in **C** confirmed on explanted heart at necropsy **(white arrow, F)**.

needle was slowly retracted under CT guidance. In the 3 animals in which intentional pneumothoraces had been created, the lung was reinflated after LV lead placement.

Repeat pacing parameters were measured immediately after needle removal and after a 30-min waiting period. Follow-up CT imaging was performed 30 min after lead placement to assess the lead position and possible complications.

After the initial tangential lead placement, the lead was removed in 4 of the first 6 animals (without intentional pneumothorax) to assess the feasibility of repeat pacemaker lead placement. A CT scan was performed 30 min after lead removal to assess potential complications before repeat lead placement.

In 3 of the 4 animals, repeat tangential lead placement was performed as described. In the fourth swine, the feasibility of a perpendicular access route was evaluated. Under real-time CT guidance, the needle was advanced along a perpendicular trajectory to the epicardium. The needle tip was advanced about 4 to 5 mm perpendicular to the epicardial surface into a midmyocardial position under real-time CT guidance, with repeat electrical recording and aspiration. Pacemaker lead placement and CT imaging were performed as described for the tangential lead placement.

Radiation exposure during the procedure was calculated on the basis of the dose-length product (DLP) recorded by the CT scanner.

Postmortem examination. At the end of the experiment, the animals were euthanized using 3 mol/; potassium chloride solution, and a midline thoracotomy was performed. The excised heart was sectioned parallel to the pacemaker lead. Lead entry point, entry angle, and length of intramyocardial lead segment were recorded for later comparison. A careful inspection for complications was performed.

Statistical analysis. Statistical analysis was performed using SPSS for Windows release 10.07 (SPSS, Inc., Chicago, Illinois). Continuous variables are expressed as mean ± SD unless noted otherwise. Comparisons were performed using a 2-tailed, 2-sample t test (analysis of variance). Correlations were assessed using Pearson's equation. Differences were considered significant at a level of $p < 0.05$.

RESULTS

CT imaging–supported planning of access strategy. In all 13 attempts, CT imaging allowed the visualization of the individual cardiac and pulmonary anatomy to plan the access strategy. An anterolateral entry site avoiding lung tissue was successfully identified in the first 6 animals (Fig. 1A). After

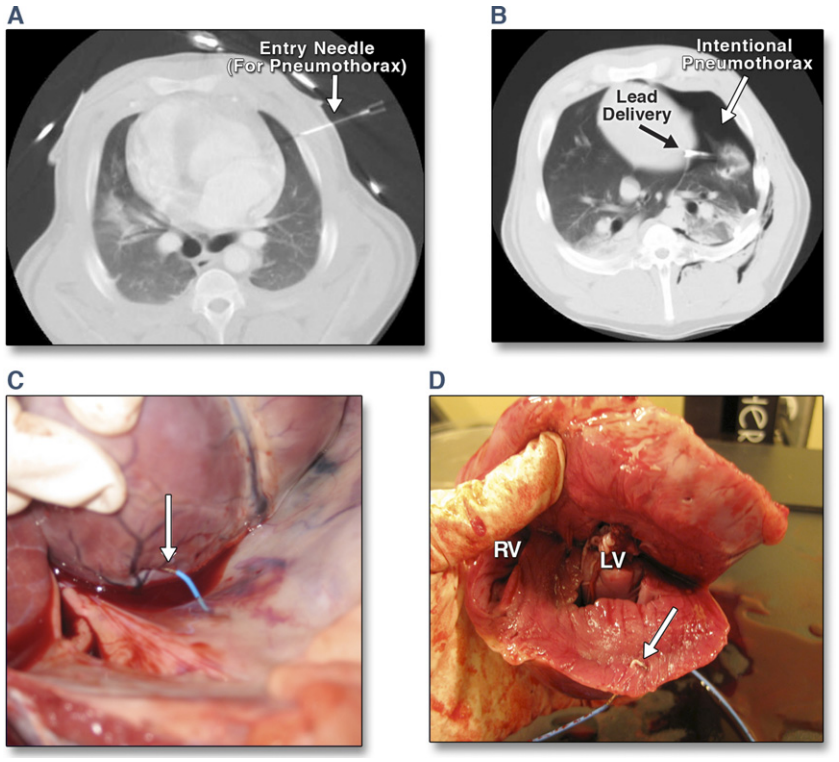

Figure 2. Real-Time CT Imaging–Guided Creation of Left-Sided Pneumothorax and Posterolateral Lead Placement

Needle at left pleural space for creation of intentional pneumothorax **(white arrow, A)**. Left-sided pneumothorax **(white arrow, B)** pacing lead delivered to the posterolateral left ventricular wall **(black arrow, B)**. Percutaneous pacing lead at necropsy **(white arrow, C)**. Posterolateral lead tip position confirmed in midmyocardium **(white arrow, D)**.

successful creation of a controlled left-sided pneumothorax under CT guidance, a lateral access site was chosen in 3 swine (Fig. 2A). The mean distances from the skin to the epicardial surface were 3.8 ± 1.7 cm and 6.3 ± 1.9 cm in the anterolateral and lateral approaches, respectively.

Real-time CT guidance to LV target site. The delivery needle could be well visualized compared with the other cardiac and pulmonary structures. Intravenous contrast injection aided in the visualization of the myocardium.

Real-time CT was successful in all experiments to guide the course of the needle from the skin surface to the epicardium along the planned trajectory. The maximal distance between the intended route (Fig. 1A) and actual trajectory (Fig. 1B) differed by <5 mm when evaluated by visual assessment and quantitative on-screen measurements. Epicardial contact of the needle tip as assessed by CT imaging could be confirmed in all experiments by the appearance of ventricular signals and the inability to aspirate blood.

In the 12 tangential approaches (9 initial and 3 repeat placements), the needle was successfully advanced to a midmyocardial position presenting 50% to 60% of the transmural thickness. Anterolateral access was usually successfully achieved during the first attempt, while 2 of the 3 lateral approaches required a second attempt. Lack of perforation was confirmed with electrographic recording and aspiration in all cases.

Percutaneous pacing lead delivery. In the 12 tangential approaches, the 3.5-F lead was successfully delivered under real-time CT guidance. CT imaging allowed the successful intramyocardial lead tip placement (bright metal artifact extending beyond the needle tip). The delivery needle could be successfully removed without acute lead dislodgement in all cases (Fig. 1C). Final intramyocardial placement was confirmed in all 12 tangentially placed pacemaker leads by electrograms and CT imaging (Figs. 1C and 3, Online Video 1).

During the single perpendicular placement, the needle was slowly advanced to a midmyocardial position representing 6 mm of the 12-mm wall thickness under real-time visualization. After several cardiac cycles, the needle tip could be visualized

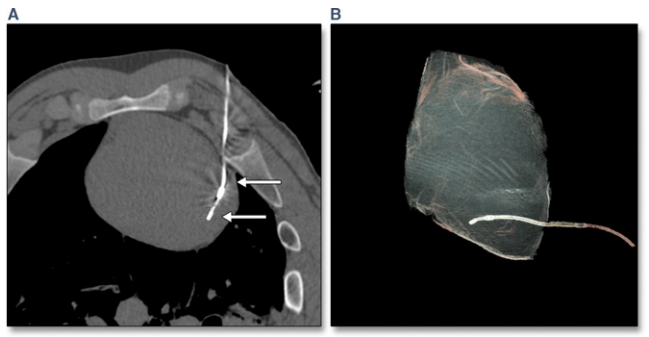

Figure 3. Left Lateral Left Ventricular Lead Placement

Intramyocardial lead can be easily detected **(white arrows, A)**. Three-dimensional reconstruction allows improved appreciation of cardiac anatomy **(B)**.

at the endocardial border, and aspiration of highly oxygenated blood with an oxygen saturation > 95% confirmed the perforation. After retraction of the needle, the artifact of the freely moving pacemaker lead could be visualized in an intracavitary position (Fig. 4). Electrographic recordings demonstrated far-field R waves and a lack of capture at 10 V at 0.5 ms. The pacemaker lead was then withdrawn to a midmyocardial position under real-time CT guidance.

Total mean procedure time was 19 ± 7 min. Mean time from percutaneous access to successful lead delivery was 14 ± 5 min for the 10 anterolateral lead placements and 34 ± 13 min for the posterolateral lead placement (pneumothorax creation: 18 ± 6 min; lead placement: 16 ± 7 min).

LV pacing. Successful LV pacing was demonstrated after all 12 tangential and the perpendicular pacemaker lead placements (Fig. 5). The mean threshold was 2.2 ± 1.3 V at 0.5 ms (range: 0.7 to 5.0 V), the mean R-wave amplitude was 10.6 ± 4.8 mV (range: 5.0 to 20.4 mV), and the mean pacing impedance was 674 ± 91 Ω (range: 509 to 814 Ω) (Table 1). No evidence of diaphragmatic or skeletal muscle stimulation was observed with pacing at 10 V at 0.5 ms. Parameters did not change significantly before and after removal of the delivery needle (Table 1). No significant change after a 30-min follow-up period was seen in the tangentially placed pacemaker leads. Pacing parameters of the 3 repeat tangential placements were similar to the 9 initial tangential placements (Table 1). Midmyocardial lead placement after the perforation (perpendicular approach) demonstrated normal immediate R-wave and pacing threshold, with rapid deterioration due to a pericardial effusion.

CT follow-up. Stable midmyocardial lead position was observed on CT imaging 30 min after the 12 tangential lead placements, and no intrathoracic hemorrhage, unintentional pneumothorax, or pericardial effusions were seen. Unchanged lead position on CT imaging was documented after 30 min in all animals, without significant changes in lead parameters. A large pericardial effusion was observed 10 min after the perforation related to the perpendicular lead placement. A real-time CT imaging–guided pericardiocentesis was successfully performed, but the animal was euthanized after reaccumulation.

Radiation dose. Localization and marker placement scans accumulated a mean DLP of 140.7 ± 17.5 mGy · cm. Placement of the LV lead scans accumulated a mean DLP of 422.1 ± 23.5 mGy · cm. Mean total procedure-related DLP was 562.8 ± 42.8 mGy · cm. This would correspond in a 70-kg reference patient to an expected whole-body effective dose of 2.4 ± 0.3 mSv (240 mrem) for localization and marker placement, 7.2 ± 0.4 mSv (720 mrem) for placement of the LV lead, and a total procedural dose of 9.6 ± 0.4 mSv (960 mrem).

Correlation of CT and pathological findings. The overall CT location of the epicardial pacing lead correlated well with the necropsy findings (Figs. 1 and 2). Mean distances of the lead tip to the right ventricular–interventricular septal junction were 40 ± 7 and 43 ± 7 mm (range: 29 to 52 mm; $p < 0.05$) by necropsy and CT imaging, respectively. Similarly, there was a significant relationship between the intramyocardial pacing lead segment by CT imaging and by pathology (15 ± 2 mm vs. 17 ± 3 mm, $p < 0.05$) (Fig. 1).

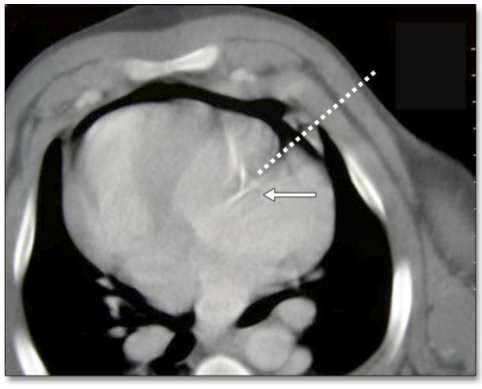

Figure 4. LV Perforation

After perpendicular access **(white dotted line)** pacing lead is seen inside the left ventricular (LV) cavity **(white arrow)**.

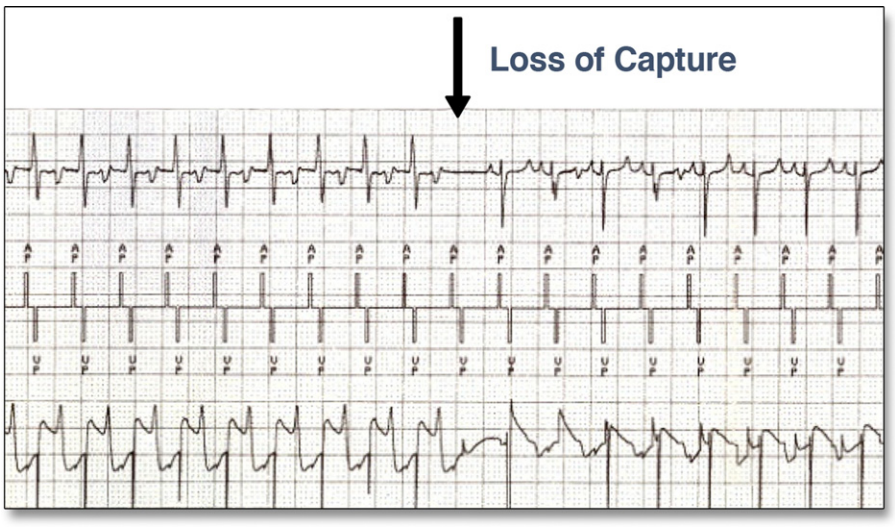

Figure 5. Ventricular Capture Threshold

Ventricular pacing at 110 beats/min **(left half of panel)** with loss of capture **(black arrow)** at a threshold of 0.8 V at 0.5 ms.

The pericardial effusion and residual pneumothoraces diagnosed on CT imaging were confirmed by necropsy. No other complication was seen in the other experiments.

DISCUSSION

To our knowledge, this is the first time that real-time CT imaging has been used to guide any interventional cardiac procedure. Real-time CT imaging was able to: 1) define and create (i.e., intentional pneumothorax) percutaneous access routes to the LV epicardium; 2) guide initial and repeat LV lead placements with acceptable pacing parameters; and 3) assess intraprocedural complications.

Clinical CS lead placement. An increasing number of studies have demonstrated improvements in morbidity and mortality with biventricular pacing in patients with NYHA class III or IV symptoms, ejection fractions ≤ 35%, and QRS durations ≥

Table 1. Pacing Parameters Shown for Each of the 12 Lead Implants

	Threshold (V at 0.5 ms)			R-Wave Amplitude (mV)			Impedance (Ω)		
Implant	IMM	NR	30 min	IMM	NR	30 min	IMM	NR	30 min
1 (AL/T)	2.4	2.3	2.1	13.9	14.0	14.6	619	632	599
2 (AL/T)	0.7	0.7	0.8	20.4	20.1	21.2	509	514	535
3 (AL/T)	5.0	4.7	4.7	6.4	6.4	7.1	721	714	698
4 (AL/T)	2.9	3.0	2.9	5.0	5.2	4.9	786	762	771
5 (AL/T)	2.0	2.3	2.1	3.8	3.4	4.5	599	634	578
6 (AL/T)	1.7	1.6	2.0	7.1	7.8	8.9	705	714	692
7 (PL/T)	3.2	3.0	2.8	14.6	12.3	9.8	628	601	590
8 (PL/T)	0.5	0.5	0.8	8.5	8.1	9.4	771	802	834
9 (PL/T)	1.2	1.1	0.9	9.7	7.8	11.2	583	602	571
10 (AL/T)	0.8	0.8	0.9	15.9	16.9	15.0	691	684	703
11 (AL/T)	3.1	3.3	3.0	9.1	10.4	10.4	814	801	799
12 (AL/P)	2.3	2.3	NA	7.9	6.8	NA	661	682	NA
Mean	2.2	2.1	2.1*	10.2	9.9	10.6*	673.9	678.5	670.0*
SD	1.3	1.3	1.2	5.0	5.0	4.8	91.2	86.8	102.0

Parameters are shown immediately after fixation of pacing lead (IMM), after needle was retracted (NR), and after a 30-min waiting period. Perpendicular placement (implant 7) led to a pericardial effusion with no measurements at 30 min (NA). Implants 1 to 9 were initial attempts, and implants 10 to 12 were repeat placements (see text). *$p > 0.05$ for comparison of 30 min versus IMM and 30 min versus NR.

AL = anterolateral lead position; P = perpendicular access; PL = posterolateral lead position after intentional pneumothorax; T = tangential.

120 or 130 ms (6). Additionally, even some patients with NYHA class I or II symptoms benefit from cardiac resynchronization (4).

Although in several studies, intravenous CS lead placement could not be achieved in up to 10% of patients (6), this number is further decreasing because of operator experience and the use of preprocedural imaging such as CT angiography. However, difficult anatomy, phrenic nerve capture, insufficient lead stability, or pacing parameters continue to be implicated in possible delivery failures (10). Even after successful CS lead placement, >30% of patients do not experience significant symptom reduction (5,11). Although early studies seemed to suggest benefit from a posterolateral lead position (7,8), recent data from the MADIT-CRT (Multicenter Automatic Defibrillator Implantation Therapy With Cardiac Resynchronization Therapy) and COMPANION (Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure) trials found no difference among anterior, lateral, and posterior pacing locations (12,13). Importantly, best locations are often defined not anatomically but by viability ("paceability"), and activation sequences using electrograms or cardiac ultrasound are able to define areas of late activation or contraction (8,14,15).

Although minimally invasive surgical approaches are forthcoming (16,17), this approach is more invasive and associated with increased morbidity but can be performed with direct visualization of the heart (18).

Percutaneous real-time CT imaging–guided approach. A percutaneous delivery of an LV pacing lead would theoretically allow the pacing lead delivery at any chosen LV site, and the lead could be tunneled subcutaneously to the subclavicular implant location. Using real-time CT imaging, the safest and most promising trajectory could be determined on the basis of the individual pulmonary and cardiac anatomy in our experiments. Access routes with no lung tissue could be selected. Although this resulted mostly in an anterolateral lead position, this location seems to be equivalent to lateral and posterior lead positions on the basis of MADIT-CRT and COMPANION results (12,13) and avoided a very apical position, which was associated with increased risk for heart failure or death (13). Additionally, our study demonstrated as proof of concept the ability to access large parts of the LV free wall after the creation of a controlled left-sided pneumothorax. The creation of controlled pneumothoraces has been used successfully for other interventional radiology procedures (19).

For further clinical trials, the development of less traumatic tools than the needle and pacing lead used in these experiments is easily conceivable. The concern of coronary artery injury could be addressed by performing intraprocedural coronary CT angiography. Similarly, delayed enhanced CT images could be used to define and avoid areas of LV scar. Importantly, complications such as perforations can be easily detected and addressed.

To our knowledge, real-time CT imaging has never been used for any cardiac interventions. However, several studies have demonstrated the high utility in various fields, such as interventional radiology and oncology. Real-time CT imaging was able to accurately guide biopsy, aspiration, drainage, and ablation in the brain, chest, and abdomen (20,21). For cardiac applications, real-time CT imaging offers the unique ability to visualize the detailed thoracic and cardiac anatomy as well as interventional tools with submillimeter resolution and, if needed, high temporal resolution. Different from real-time magnetic resonance imaging applications, all devices clinically used and approved by the U.S. Food and Drug Administration can be readily used, because heating, electromagnetic signal noise, and ferromagnetic materials present no substantial safety concern for real-time CT imaging.

Radiation exposure. When translating the results to a 70-kg reference patient, a total effective dose of 9.6 mSv is about half that of coronary angioplasty, equivalent to CT imaging for pulmonary embolism and in the range of CT imaging of the liver or kidneys (22–25). This might be acceptable radiation exposure given the demonstrated mortality and morbidity benefit of resynchronization therapy. Additionally, advances in CT technologies, such as prospective gating, iterative reconstruction, tube current modulation, and low–tube voltage protocols, allow even further dose reductions in new CT scanner systems (26). Especially the variants of iterative image reconstruction currently introduced into routine scanning procedures are promising for drastic dose reductions in the range of 50% and higher, without significant changes to the achievable image quality.

Study limitations. Given the scope of this feasibility study, the number of study animals was limited. Additionally, species-specific differences in LV wall thickness between swine and humans may also influence the safety of a percutaneous approach.

The stability of the pacing parameters was tested only during a 30-min period and may become less stable during long-term follow-up. Although complete reinflation of the left-sided intentionally created pneumothorax was attempted, the lack of continuous suction through a chest tube resulted in a residual pneumothorax.

No exact intracardiac location markers, such as surgically implanted metal beads, were used to assess the accuracy of the real-time CT imaging–guided placement. However, the overall location (anterolateral or posterolateral wall), septum–to–lead tip distance, and length of intramyocardial segment suggest a good correlation between real-time CT imaging and necropsy findings.

Registration of the 2-dimensional imaging plane used for needle navigation to the 3-dimensional imaging matrix would provide additional improved guidance to the best target site and may help even further to avoid possible complications such as nerve or vascular damage.

CONCLUSIONS

To our knowledge, this is the first study using real-time CT imaging to guide any cardiac intervention. This study demonstrates the feasibility of percutaneous LV lead placement, with acceptable procedure times and good pacing parameters. Real-time CT imaging allowed planning of the trajectory, visualization of pacing lead deployment, and early detection of complications. This strategy may offer an alternative to surgical procedures after failed attempts at endocardial CS lead placement.

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Key Words: computed tomography ■ left ventricular pacing ■ percutaneous access ■ real-time guidance.

APPENDIX

For the supplementary video and its legend, please see the online version of this article.