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Fully Percutaneous Transthoracic Left Atrial Entry and Closure as a Potential Access Route for Transcatheter Mitral Valve Interventions

Toby Rogers, BM BCh, MRCP*, Kanishka Ratnayaka, MD*,†, William H. Schenke, BA*, Merdim Sonmez, PhD*, Ozgur Kocaturk, PhD*,‡, Jonathan R. Mazal, MS*, Marcus Y. Chen, MD*, Moshe Y. Flugelman, MD§, James F. Troendle, PhD||, Anthony Z. Faranesh, PhD*, and Robert J. Lederman, MD*

*Cardiovascular and Pulmonary Branch, Division of Intramural Research, National Heart Lung and Blood Institute, National Institutes of Health, Bethesda, MD

†Department of Cardiology, Children's National Medical Center, Washington DC

‡Institute of Biomedical Engineering, Bogazici University, Istanbul, Turkey

§Department of Cardiology, Carmel Medical Center, Haifa, Israel

||Office of Biostatistics Research, Division of Cardiovascular Sciences, National Heart, Lung and Blood Institute, National Institutes of Health, Bethesda, MD

Abstract

Background—Percutaneous access for mitral interventions is currently limited to transapical and transseptal routes, both of which have shortcomings. We hypothesized that the left atrium could be accessed directly through the posterior chest wall under imaging guidance.

Methods and Results—We tested percutaneous transthoracic left atrial access in 12 animals (10 pigs and 2 sheep) under real-time MRI or X-ray fluoroscopy plus C-arm CT guidance. The pleural space was insufflated with CO₂ to displace the lung, an 18Fr sheath was delivered to the left atrium, and the left atrium port was closed using an off-the-shelf nitinol cardiac occluder. Animals were survived for a minimum of 7days. The left atrium was accessed and the port was closed successfully in 12/12 animals. There was no procedural mortality and only one hemodynamically insignificant pericardial effusion was observed at follow-up. We also successfully performed the procedure on three human cadavers. A simulated trajectory to the left atrium was present in all of 10 human cardiac CT angiograms analyzed.

Conclusions—Percutaneous transthoracic left atrium access is feasible without instrumenting the left ventricular myocardium. In our experience, MRI offers superb visualization of anatomic structures with the ability to monitor and address complications in real-time, although X-ray guidance appears feasible. Clinical translation appears realistic based on human cardiac CT

Correspondence to Robert J. Lederman, MD, National Heart Lung and Blood Institute, National Institutes of Health, Building 10, Room 2c713, Bethesda, MD 20892-1538, USA. Telephone: +1-301-402-6769. lederman@nih.gov.

Disclosures
None.

analysis and cadaver testing. This technique could provide a direct non-surgical access route for future transcatheter mitral implantation.

Keywords

structural heart disease; magnetic resonance imaging; cardiac valvular surgery; mitral valve; transapical; interventional MRI; transcatheter mitral valve replacement; percutaneous mitral valve repair

Transcatheter mitral valve-in-valve or valve-in-ring implantation is feasible using prostheses designed for the aortic valve^{1, 2}. Implantation in the native mitral annulus presents distinct challenges: available aortic prostheses are too small, valve fixation is difficult because the annulus is elastic, and the sub-valvular apparatus, which plays an important role in left ventricular function, should not be disrupted. At least four dedicated devices have undergone early human testing³⁻⁵. These are bulky and require large caliber access ports (up to 32Fr), mostly transapical.

Whether transapical access is associated with higher mortality than transfemoral remains unclear⁶⁻⁸. The higher mortality reported in some studies may reflect inclusion of higher risk patients or operator experience. Nonetheless, magnetic resonance imaging (MRI) and echocardiography detect apical wall motion abnormalities after transapical access, particularly in patients with increased left ventricle (LV) diameter, which can lead to long-term reduction in global LV function⁹⁻¹¹. In the PARTNER trial quality-of-life assessment, transcatheter aortic valve replacement via transapical approach demonstrated no benefit compared with conventional surgery¹². Morbidity and mortality are likely even higher in patients with mitral valve disease because of preexisting LV dysfunction. Truly percutaneous transapical access using nitinol devices for closure is possible¹³, but complications do occur including pneumothorax, cardiac tamponade, LV pseudoaneurysm and hemothorax related to coronary or intercostal vessel laceration or bleeding from the LV puncture site¹⁴.

Alternative approaches have been explored for mitral valve interventions: direct trans-atrial via mini-thoracotomy¹⁵, transjugular transseptal^{16, 17}, and transfemoral transseptal¹⁸. However, a mini-thoracotomy still confers surgical morbidity. Transseptal delivery of large mitral implants has been demonstrated, but achieving coaxiality with the mitral valve can remain challenging. A 'straight shot' to the mitral valve that permits large sheath access but does not violate the LV myocardium would be desirable, and could reduce the engineering constraints of miniaturization, reduce procedural complexity and improve patient outcomes.

Percutaneous left atrial (LA) access was first performed in the 1950s using long needles through the posterior chest wall to sample pressure^{19, 20}. At first glance, delivering large sheaths via this approach appears challenging because of interposed lung, but there is extensive surgical evidence that temporarily collapsing a lung to perform an intra-thoracic intervention is safe²¹. In fact, diagnostic thoracoscopy with iatrogenic lung deflation is commonly performed in awake patients and confers extremely low morbidity and mortality²². Percutaneous transthoracic cardiac catheterization has also been performed in

children with no alternative access, through the anterior chest into the pulmonary venous atrium and through the lower back into the inferior vena cava^{23, 24}.

We hypothesized that with imaging guidance and percutaneous techniques, it is possible to access the LA directly through the posterior chest wall by first displacing a lung with gas, then delivering a large sheath, and finally closing the LA port using off-the-shelf nitinol cardiac occluder devices. Compared with percutaneous transapical LV closure, we believe that closing a port in the lower pressure LA may be preferable. Because of anatomic differences between large mammals and human, we tested this hypothesis in two different large animal models (porcine and ovine) and then explored feasibility of clinical translation with human cardiac computed tomography (CT) analysis and human cadaver testing. We also explored different image guidance modalities, MRI and X-ray fluoroscopy, to simplify translation into patients.

Methods

Animal experiments

The institutional animal care and use committee approved all procedures, which were performed according to contemporary NIH guidelines. Animals were anesthetized with ketamine (25mg/kg), midazolam (15mg/kg) and glycopyrrolate (0.01mg/kg), and maintained with on sevoflurane (1–4%) with and mechanical ventilation. Femoral arterial and venous access was obtained with ultrasound guidance with animals supine.

The technique was developed in non-survival experiments on 10 naïve Yorkshire swine, not further described here. Subsequently, survival experiments were performed in 10 naïve Yorkshire swine with median bodyweight 51kg (47–54kg) and 2 naïve Dorset sheep (28kg, 36kg), all of which were survived for at least 7days before euthanasia and necropsy.

Imaging

Experiments were performed first using MRI at 1.5T (*Aera*, Siemens) and later using biplane X-ray fluoroscopy enhanced by C-arm CT (*Artis Zee* and *DynaCT*, *Siemens*). Experiments are summarized in Figure 1. For MRI, trajectories were planned on isotropic 3D images, and the procedure was performed using custom MRI-antenna needles²⁵ and real-time MRI at frame rates up to 15fps. MRI parameters and devices are provided in the data supplement.

Pericardial auto-transfusion catheter placement

An 8.3Fr multi-sidehole subxiphoid pericardial drain was placed after trans-atrial microcatheter CO₂ insufflation as described²⁶, and connected to the femoral vein to facilitate immediate auto-transfusion for blood salvage. 500–1000IU of unfractionated heparin was infused into the pericardial space to prevent in situ thrombus.

Pleural CO₂ insufflation to displace lung

A needle was advanced through the left lateral chest wall during small puffs of iodinated or gadolinium contrast (for X-ray or MRI visualization, respectively) until the pleural space

was entered (Figure 2). This was exchanged for an 8.3Fr multi-sidehole pleural drain positioned in a dependent position to aspirate fluid but not CO₂. As with the pericardium, 500–1000IU of unfractionated heparin was infused into the pleural space to prevent in situ thrombus formation and facilitate auto-transfusion. The pleural space was insufflated with CO₂ titrated to displace lung sufficiently to allow a clear trajectory to the LA. After insufflation, the ventilation rate was increased and tidal volumes reduced to keep airway pressure low.

Transthoracic left atrial trajectory planning and access

3D MRI or X-ray (C-arm CT and biplane fluoroscopy contrast angiograms) of the LA was acquired at baseline and after pleural insufflation. For X-ray guidance we used a superimposed C-arm CT of LA and LV angiograms (syngo InSpace EP, *Siemens*). Swine and sheep were positioned respectively on the right side or prone, to optimize working angles. A 20cm needle was used to puncture through the posterior or lateral chest wall, pass through the empty pleural space, and enter the LA posteriorly (Figure 3, Figure 4). Needle tip position was confirmed by atrial pressure waveform and contrast injection. A stiff nitinol guidewire (Nitrex, *Covidien*) was introduced through the mitral valve to the LV apex, over which a 18Fr sheath (outer diameter 7mm, Large Check-Flo, *Cook*) and a custom-shortened dilator was advanced into the LA without pre-dilatation. Sheath position and relation to the mitral valve were confirmed using MRI or biplane contrast angiography.

Left atrial closure

The LA port was closed with an off-the-shelf 5 or 6mm nitinol atrial septal occluder (*St Jude Medical, MN; Lepu Medical, Beijing, China*). The distal disc was deployed within the LA and the sheath and delivery catheter were withdrawn in tandem until the disc was in apposition with the LA wall. The proximal disc was deployed outside the heart within the pleural space and the device was released.

Human cadaver study and human CT analysis

To explore feasibility for humans, we tested percutaneous transthoracic LA access and closure in three human cadavers (one under MR and two under X-ray guidance). After femoral access, the cadavers were rolled prone and all procedural steps were identical to those previously described for animal procedures, using a larger sheath (*Ascendra, Edwards Lifesciences*, 26Fr/30Fr inner/outer diameter).

We also examined 10 random cardiac CT angiograms having full chest wall coverage among patients with mitral valve disease, dilated LA, or previous sternotomy in the NHLBI anonymized and de-linked database. This does not constitute human subjects research under US 45CFR§46.102(f). Each CT was examined for potential trajectories to the LA.

Statistical analysis

Hemodynamic data are reported in the Table as median with first and third quartiles (Q1–Q3). Each hemodynamic parameter was analyzed in a linear mixed model with ARMA(1,1) correlation structure assumed within each animal. The model fit mean levels of each parameter at each of the four post-baseline follow-up measurements with baseline as the

reference. Since there were four follow-up measures for each of three hemodynamic parameters we used a Bonferroni correction factor of 12 to account for multiple comparisons. A multiplicity-corrected p value 0.05 was considered statistically significant.

Results

Pericardial access for auto-transfusion catheter placement

Trans-atrial pericardial access with a 2.8Fr microcatheter, insufflation of the pericardial space with CO₂, placement of a sub-xiphoid 8.3Fr drain and withdrawal of the trans-atrial microcatheter was uncomplicated in all 12 animals.

Pleural insufflation

Pleural access and left lung deflation with CO₂ was uncomplicated in all 12 animals. 600–900mL of CO₂ was required to displace the lung sufficiently to establish an unobstructed trajectory to the LA in both species. Pleural pressures remained low (8–10mmHg) and, despite lung displacement, ventilation was well tolerated with no increase in expired CO₂ or evidence of hemodynamic compromise (Table). Reductions in mean arterial pressure and heart rate were observed after pleural insufflation, which were likely caused by an increase in the inhaled anesthetic agent concentration required to allow for the reduction in ventilator tidal volumes. However, these changes were not statistically significant.

Trajectory planning

In swine, pleural insufflation caused the heart to rotate, displacing the long axis of the LV by 7° (6–14°) compared with baseline. A direct trajectory to the LA, avoiding important anatomic structures was achievable in all animals. Distance from skin to LA was 10cm (9–11cm) in swine and 11cm in both sheep.

Transthoracic left atrial access and closure

The LA was successfully accessed in 10/10 swine, including 8 under MR guidance (Figure 3, Video 1) and 2 under X-ray guidance (Figure 4, Video 2). All succeeded in a single needle pass except in one, wherein a custom needle that had become ‘dull’ required a second pass. The stiff nitinol guidewire was positioned in the LV apex, over which the 18Fr sheath was advanced without pre-dilation. Sheath advancement displaced the LA wall by 25mm (20–30mm) (under X-ray guidance), but the wall recoiled as soon as the sheath tip entered the LA. No pericardial or pleural effusions developed during LA puncture or while the large sheath remained in place. 3D and cine MRI confirmed that the sheath trajectory was offset relative to the long axis of the LV by an angle α of up to 30° (Figure 3). The LA port was successfully closed with a single nitinol cardiac occluder device in all animals. During sheath withdrawal and LA port closure, accumulated blood was auto-transfused intermittently using the pre-positioned pericardial and pleural drains. Median pericardial and pleural auto-transfusion volumes were 55mL (40–73mL) and 10mL (10–75mL) respectively. Animals were stable hemodynamically throughout and no arrhythmias were observed (Table).

The LA was successfully accessed with a single pass and closed under MRI guidance in 2/2 sheep. One animal had minimal pericardial effusion (50mL). The second required higher than expected intra-procedural auto-transfusion (300mL) without any hemodynamic compromise. Pleural effusion was negligible in both animals (10ml and 20mL).

There was no procedural mortality and all animals recovered uneventfully. At the end of the procedure, the pericardial and pleural spaces were aspirated to dryness, any remaining pleural CO₂ was aspirated and the drains were withdrawn.

Follow up

No complications were observed during the follow up period of 7.5days (7–8.5days). Follow up MRI confirmed stable position of the LA occluder device in all animals. 12/12 animals had no pleural effusion. 11/12 animals had no detectable or trace pericardial effusion 0mL(0–6mL). One pig, in which the LA was punctured twice, had a large but hemodynamically insignificant pericardial effusion (660mL) at 7days follow up. No other complications were observed in any animal and all skin incisions healed well. On necropsy, the nitinol cardiac occluder device was well seated and fibrosed to the LA wall in all animals (data not shown).

Human CT analysis

Cardiac CT angiograms from 10 patients (age 68years (59–73years), 8/10 male) with full chest wall coverage were examined. A direct trajectory to the LA through the right posterior chest wall was achievable in all (Figure 5, Video 3). The right lung would need to be displaced by pleural insufflation, but the trajectory avoided important structures including descending aorta and esophagus. The mean angle α between the achievable trajectory and the true long axis of the LV was 5° (4–7°). Mean intercostal distance at the point of entry through the chest wall was 12mm (11–15mm).

We also tested whether there was a trajectory to the mitral valve from a right mini thoracotomy incision, entering the right atrium, and passing through the interatrial septum. In all 10 patients this was achievable but the offset angle between the trajectory and the true long axis of the LV was 56° (51–58°).

Human cadaver study

In the prone position, right pleural insufflation and deflation of the right lung was straightforward whether under MR or X-ray guidance. This exposed a direct trajectory to the posterior wall of the LA avoiding other important structures, such as aorta and esophagus in all three cadavers. The LA was successfully entered and a large 26Fr sheath was delivered. Pleural insufflation did not cause the heart to shift orientation within the thorax. As a result, the sheath trajectory remained well aligned with the long axis of the LV. The LA port was closed using a nitinol cardiac occluder device and the right lung was re-inflated by aspirating the pleural CO₂ (Figure 6, Video 4).

Discussion

We describe a novel percutaneous technique to access the left heart to deliver interventional devices. The technique combines several innovations: (1) Fully percutaneous transthoracic LA access with a needle followed by a large sheath; (2) Pericardial auto-transfusion catheter placement; (3) Pleural insufflation and lung displacement to create an unobstructed trajectory to the LA; and (4) Closure of the LA port using off-the-shelf nitinol cardiac occluder devices. We demonstrated pre-clinical feasibility in two large animal models (porcine and ovine) and feasibility of clinical translation through performing the procedure in human cadavers and simulating on human cardiac CT images. Real-time MRI provided optimum usability, for example continuous depiction of the deflated lung, but X-ray fluoroscopy assisted by C-arm CT provided adequate confirmation of lung displacement during sheath traversal of the pleural space for LA entry.

Pleural insufflation to create unobstructed trajectory to LA

Thoracoscopy to inspect the pleura, perform biopsy or deliver therapy is an established technique usually performed under moderate sedation²⁷. More advanced procedures, for example lobectomy or management of spontaneous pneumothorax, are typically performed under general anesthesia with dual-lumen endotracheal tube to facilitate single lung ventilation, and have excellent peri-operative outcomes^{21, 28, 29}. However there is evidence that such interventions can be well tolerated in conscious non-intubated patients³⁰ even for long procedures and in older sicker patients³¹. Based on this extensive clinical experience, there is reason to expect that single lung deflation for the purpose of transthoracic LA access may be tolerated in patients.

Choice of imaging modality to guide LA access

The superior soft tissue visualization and multiplanar viewing capabilities of MRI is appealing to guide minimally invasive interventions, particularly interventions that violate vascular boundaries, in which every anatomic structure traversed must be visualized. MRI provides this capability. In this study, we demonstrated that LA access and closure could be safely performed using real-time MRI guidance. MRI also permitted easy access to the pleural space and titration of pleural insufflation to displace lung. Crucially, MRI afforded continuous monitoring for development of pericardial and pleural effusions during LA puncture and closure. Any accumulation of blood in the pericardial or pleural space was immediately identified and auto-transfused.

Nonetheless, we explored whether the procedure could be performed using X-ray fluoroscopy. A transseptal pigtail catheter was positioned in the LA. Biplane contrast angiography and intra-pericardial iodinated contrast delineated LA anatomy adequately. This enabled a trajectory to the LA to be planned in orthogonal X-ray projections. It was difficult to definitely establish adequate lung displacement using fluoroscopy only, but C-arm CT provided clear visualization of lung tissue and assurance of satisfactory lung displacement. In humans, where the preferred LA puncture site should be posterior and mid-way between left and right pulmonary vein ostia, dual transseptal guidewires in left and right pulmonary veins could offer a precise fluoroscopic target for LA puncture.

Echocardiography could provide a substitute for real-time MRI to monitor for pericardial blood accumulation and guide auto-transfusion.

We also explored using color overlays of the LA and LV, segmented from contrast-enhanced C-arm CT using software designed to guide electrophysiological procedures. The fusion images enhanced our ability to predict trajectories and determine optimal LA puncture location (Figure 4). Additionally, the overlays aided in selecting optimal X-ray projection angles and may have reduced overall iodinated contrast usage.

Closure of LA port

There is clinical precedent for the use of off-label nitinol cardiac occluder devices to seal large holes in vascular structures, including the LV apex or abdominal aorta^{13, 32}. Even in the high pressure LV, hemostasis was rapidly achieved with reversal of anticoagulation. Hemostasis should be easier to achieve in the LA because the pressure is much lower than in the LV or systemic arteries, even in patients with mitral valve disease. In some animals, blood did accumulate in the pericardial or pleural space, but was easily managed by aspiration and auto-transfusion, akin to standard surgical blood salvage technique. After aspirating to dryness, all drains were removed post procedure for animal comfort – although in humans they would be left in overnight. Only one large but hemodynamically insignificant pericardial effusion was observed at follow up, in the one animal in which two LA punctures were made because a custom needle had become ‘dull’. The animal recovered uneventfully and the effusion would not have accumulated had the pericardial drain remained in place immediately post-procedure.

Feasibility of clinical translation

We tested LA access and closure in two large animal models in order to determine whether the approach was feasible in different anatomies. The trajectories for unobstructed access to the LA were different in the two species but easily achievable by deflating the left lung. Importantly, all animals were hemodynamically stable with a large sheath in the LA. This approach could circumvent many of the risks associated with trans-apical access in patients with advanced mitral valve disease, in particular acute hemodynamic instability and late LV pseudoaneurysm, ventricular arrhythmias and decrement in LV function.

Human cardiac CT angiogram analysis confirmed that a theoretical trajectory exists in humans. In swine, pleural insufflation rotated the heart in the thorax, which resulted in an offset between the long axis of the heart and the achieved trajectory (Figure 3). Because the orientation of the heart in the human mediastinum is different, the trajectory is different from that in swine or sheep. In humans, the right lung would be deflated to puncture the LA posteriorly between the pulmonary veins (Figure 5). In this configuration, right lung deflation would deflect the right pulmonary veins away from the needle trajectory, exposing the posterior wall of the LA. This trajectory avoids other important structures such as the aorta and esophagus. The mean intercostal distance at the point of entry through the chest wall was sufficient to accommodate a sheath 32Fr or larger.

To demonstrate that this trajectory was feasible, we accessed the LA in human cadavers and delivered a large sheath under either MRI or X-ray guidance (Figure 6). Pleural insufflation

did not shift the orientation of the heart within the thorax in cadavers. We then closed the LA port with a nitinol cardiac occluder device and re-expanded the right lung.

Limitations

There are anatomical differences between humans and swine. For example, the descending aorta and esophagus vary in position within the thorax. Procedural tomography (such as C-arm CT or real-time MRI) is therefore recommended for trajectory planning. Pulmonary disease or chronic heart failure could increase the risk of single lung ventilation. Clotting disorders could increase bleeding. Off-label nitinol cardiac occluder devices may not assure hemostasis. Prior cardiothoracic surgery may cause pleural adhesions, which could impede lung displacement. Because our technique involves two points of fixation (chest wall and left atrial wall), sheath maneuverability is constrained. However, because excellent alignment with the LV long axis can be achieved by careful trajectory planning, we do not anticipate that excessive sheath manipulation would be required to achieve coaxial alignment to perform a mitral valve intervention.

Technical considerations for clinical translation

To perform this procedure in patients under X-ray fluoroscopy guidance, we envision the following provisions. (1) The procedure would be performed under general anesthesia with a dual lumen endotracheal tube and/or bronchial blockers to facilitate intentional right lung collapse and single lung ventilation. (2) The patient would be positioned initially supine for standard percutaneous access and then rolled prone for transthoracic atrial access. (3) A temperature or transesophageal echocardiography probe would be used to identify the esophagus. (4) A pericardial drain may not be required in patients with prior sternotomy and pericardial adhesions. (5) Respiration would be suspended during LA puncture. (6) The guidewire would be advanced through the mitral valve into the LV over a balloon catheter to prevent chordal entrapment. (7) Anticoagulation would be reversed with protamine immediately prior to cardiac occluder device deployment. (8) A coaxial buddy wire would be used during LA port closure to allow LA access to be reestablished rapidly in case of inadvertent pull through of the nitinol cardiac occluder device. (9) Pleural and/or pericardial drains would be left in place for a short period after the procedure to drain any effusions.

Conclusion

Fully percutaneous transthoracic LA access is feasible to deliver large interventional devices to the mitral valve without violating the LV myocardium. The procedure can be guided by a variety of imaging modalities, although in our experience MRI guidance offers the greatest visualization of anatomic structures with the ability to monitor and address complications in real-time, for example pericardial effusion. Clinical translation appears feasible based on human cardiac CT analysis and human cadaver testing. This technique could provide a direct and coaxial access route for transcatheter mitral valve interventions in the future.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.
Experiment design

Figure 2. MRI guided pleural insufflation to displace lung

(A) Needle (arrow) is advanced through the chest wall towards the pleura. (B) 'Saturation mode' MRI darkens tissue to enhance visibility of gadolinium contrast. Small aliquots of contrast injected through the needle (arrow) show that the tip is still within the chest wall. (C) After advancing the needle further, contrast flows freely around the lung in the pleural space (arrows). Saturation mode MRI is then toggled off. (D, E, F) After insertion of a drain, the pleural space is insufflated with CO₂ despite positive pressure ventilation to deflate the lung. Arrows indicate lung margin during progressive pleural insufflation.

Figure 3. Real-time MRI guided left atrial access and closure in swine

(A) An active visualization MRI needle incorporating MRI electronics for enhanced visibility, is introduced through the chest wall into the empty pleural space. The tip is positioned against the posterior LA wall (arrow). (B) LA puncture: the active needle tip is clearly seen within the LA (arrow). (C) Delivery of a large 18Fr sheath into the LA. The guidewire is visible in the apex of the LV (arrow). (D) Filled with gadolinium contrast, the sheath trajectory to the LA is apparent. There is a passive marker at the tip of the sheath (arrow). The angle α represents the offset between the sheath trajectory and the long axis of

the LV (dotted red line). (E) A nitinol cardiac occluder device is loaded onto an active delivery cable, which incorporates MRI electronics for visualization. The distal disk is deployed within the LA and pulled back against the posterior wall (arrow). The proximal disk is deployed outside the heart. (F) 7 days later, the nitinol cardiac occluder device remains in the intended position, with no pericardial effusion.

Figure 4. X-ray fluoroscopy and C-arm CT guided left atrial access and closure in swine
 (A) A pigtail catheter is positioned in the LA via transseptal puncture. Contrast-enhanced cone-beam angiography is performed and LA and LV are segmented and overlaid on the fluoroscopic images. The needle tip (arrow) for LA puncture is positioned against the posterior wall of the LA. (B) The needle (arrow) is advanced into the LA. (C) A stiff wire is introduced through the mitral valve into the LV apex. (D) A large sheath is advanced over the wire into the heart. (E) After withdrawing the sheath dilator, the sheath tip is confirmed within the LA. (F) The LA port is closed with a nitinol cardiac occluder device (arrow).

Figure 5. Human cardiac CT angiography analysis

Axial (A) and sagittal (B) CT cross sections showing simulated trajectory to the left atrium (red line). The angle α represents the offset between the simulated trajectory and the true long axis of the LV. (C) 3D reconstruction showing skin entry point (yellow arrow). The LA is highlighted in green and the esophagus in purple.

Figure 6. Realtime MRI guided left atrial access and closure in a human cadaver
(A) Axial MRI before lung deflation. (B) MRI in the same plane after right lung deflation. An unobstructed trajectory to the LA is apparent. (C) Axial MRI of large sheath in the LA filled with gadolinium contrast. (D) Sagittal MRI of sheath in the LA. (E) Deployment of a nitinol cardiac occluder device (arrow). The delivery cable incorporates MRI electronics to enhance device visualization. (F) After lung re-inflation, the device can be clearly seen across the posterior wall of the LA (arrow).

Table**Hemodynamics**

Mean arterial pressure, heart rate and expired CO₂ in swine (n=10) undergoing direct percutaneous LA access. The two sheep were smaller animals with lower baseline blood pressure so were excluded from the analysis of hemodynamics. No differences retained statistical significance after correction for multiplicity.

n=10 swine	MAP (mmHg)	HR (bpm)	Expired CO₂ (mmHg)
Baseline	61(53–74)	96(77–102)	29(27–32)
After lung deflation	57(46–66)	88(72–98)	28(26–29)
After insertion of left atrial sheath	52(45–64)	87(69–97)	29(27–31)
After closure	50(47–59)	81(67–91)	31(29–33)
Follow up	56(48–72)	102(84–113)	30(30–33)

Data are presented as median (Q1–Q3). MAP: mean arterial blood pressure; HR: heart rate.