

Current and novel percutaneous epicardial access techniques for electrophysiological interventions: A comparison of procedural success and safety

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Abstract

Accessing the pericardial space safely and efficiently is an important skill for interventional cardiac electrophysiologist. With the increased recognition of the complexity of the 3-dimensional arrhythmogenic substrate due to advances in imaging and mapping technologies there has been an expansion of epicardial procedures in recent years. Equally, minimally invasive implantation of epicardial pacing, cardiac resynchronization, or defibrillation leads is expanding in specific patients where transvenous systems are contraindicated or their long term sequelae should be ideally avoided. Selective delivery of intrapericardial pharmacological antiarrhythmic therapy is yet another potential indication, albeit still investigational. The expanding indications for percutaneous epicardial procedures is contrasted by the still substantial risk and challenges associated with accessing the pericardial space. Myocardial perforation, coronary artery laceration, and damage to the surrounding organs are all recognized and feared complications. A number of innovative epicardial access techniques have been proposed to overcome the difficulties and risks of traditional dry subxiphoid punctures and may allow for more widespread use of epicardial access in the future. We review 10 different established and novel subxiphoidal epicardial access techniques describing procedural success rates, safety profile and overall experience. The technical aspects as well as access times and costs for extra equipment will be reviewed. Finally, an outlook of reported preclinical techniques awaiting in-human feasibility studies is provided.

KEYWORDS

epicardial access, epicardial mapping, needle-in-needle puncture, pericardial adhesions, pericardial carbon dioxide insufflation, pericardiostomy, subxiphoid puncture

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1 | INTRODUCTION

Percutaneous epicardial procedures have expanded substantially in recent years, including for ablation of ventricular arrhythmias and minimally invasive insertion of cardiac devices in the pericardial space.

In the vast majority of epicardial procedures, the most critical and challenging aspect relates to gaining access to the pericardial space. The increase in indications and requirements to deliver epicardial therapies has highlighted the need for new innovative epicardial access techniques to overcome the difficulties and risks associated with traditional subxiphoid puncture.

2 | ANATOMY OF THE PERICARDIAL SPACE

The pericardial space is formed by serous membranous viscerous ("epicardial") and fibrous parietal ("pericardial") layers creating a sac enveloping the heart with reflections at the sites of the great cardiac arteries and veins permitting entry and exit of the vasculature and cardiac nerves, which has been described as an invagination of the pericardial sac by the heart.¹ The pericardial space contains a small amount (<50–80 mL) of physiological serous fluid to lubricate the surface of the heart and allow free motion.² It is this thin layered space that is targeted by the percutaneous access techniques. More detailed descriptions of the anatomy of the pericardial space as relevant to the cardiac electrophysiologists have been published,^{1,3} and an illustration of the key anatomical structures in relationship to epicardial access is provided in Figure 1.

Indications for epicardial access in cardiac electrophysiology are summarized in Table 1.

3 | PERCUTANEOUS EPICARDIAL ACCESS TECHNIQUES

Safety profiles and success rates of a number of percutaneous epicardial access techniques have been published (summarized in Table 2, a detailed account of complication types and respective incidence as reported in the literature is provided in Supporting Information: Table 1). In general they can be categorized as techniques which proposed a modification of the traditional Sosa approach by using standard catheter lab tools (Micro-needle puncture, needle-in-needle, wire guided access, SAFER approach, EAMS-guided, illustrated in Figure 2), additional medical equipment required and available in the hospital but not routinely in the catheter lab (carbon dioxide insufflation, laparoscopic guided epicardial puncture) or techniques utilizing dedicated devices (EpiAccess™ System, ViaOne™ Device, Pericardial Videoscope, pericardial RF needle).

The advantage of percutaneous access strategies, opposed to surgical approaches, is the lower logistical and staffing requirement and cost, lower postinterventional morbidity with more rapid mobilization of the patient postprocedure, as well as ease of pericardial access site closure and wound care. In the vast majority of the cases, simple medical measures are sufficient for closing the puncture site (e.g.,

medical glue or wound closure strips and a dry dressing to cover the puncture site) after removal of the pericardial sheaths.

In turn percutaneous access strategies, independent of employed approach, may fail in the presence of severe pericardial adhesions, commonly seen in patients with previous cardiac surgery, epicardial ablation, thoracic radiotherapy, and/or history of pericarditis, but also in 8% without history of either of the before mentioned factors.³³ Complications arising at the time of access are the second most common reason forcing operators to abandon epicardial access. Patient-specific characteristics including hepatomegaly, megacolon, lung hyperinflation, and/or interposition directly behind the sternum or severe obesity are a number of other factors which may further pose challenges for percutaneous subxiphoid access but are usually evident upfront and should be taken into consideration when choosing an epicardial access technique.

3.1 | The Sosa approach: Traditional subxiphoid dry pericardial puncture

Direct dry pericardial puncture with a 17 or 18G Tuohy needle for epicardial access as originally described in a landmark publication in 1996 by Sosa et al.³⁴ remains the reference to which new approaches are being compared. Multiple large single and multicenter studies have reported its use with success rates between 90%–98% and major access related complications rates of 4.1%–11.3% with no significant change over the past decade. Complications are predominantly driven by pericardial bleeding due to iatrogenic myocardial perforation or less commonly coronary laceration followed by injury of the abdominal organs (see Table 2). Of note, reported success and complication rates relate to high volume tertiary centers with experienced operators. No dedicated equipment for epicardial access is required and the reported access time is short (around 5 min¹⁶ for the puncture itself).

3.2 | Microneedle puncture (MNP) and "Needle in Needle (NIN)" epicardial access

To reduce access related complications, the use of a thinner (21G) micropuncture needle (MPN) with smooth shaft-to-tip transition opposed to the traditional large bore (17) needle has been proposed.¹⁷ The smaller surface of tip may allow it to pass through the fibrous pericardium with less force and even in case of inadvertent ventricular puncture, perforations are more likely to auto seal. A telescopic approach, or "needle in needle," using a short large bore needle has been suggested to support the MNP and prevent bending in the subcutaneous tissue. A possible downside of MNPs is operators reported less tactile feedback during the puncture. Yet, in the two largest published case series (see Table 2) success rates were very high and major bleeding complications requiring intervention substantially lower compared to the traditional puncture technique, despite an equivalent high rate of inadvertent RV punctures. The latter highlights the safety benefits of using a thinner less traumatic needle, generally available in a cardiac interventional labs, and easy to implement with minimal changes to the procedural workflow.

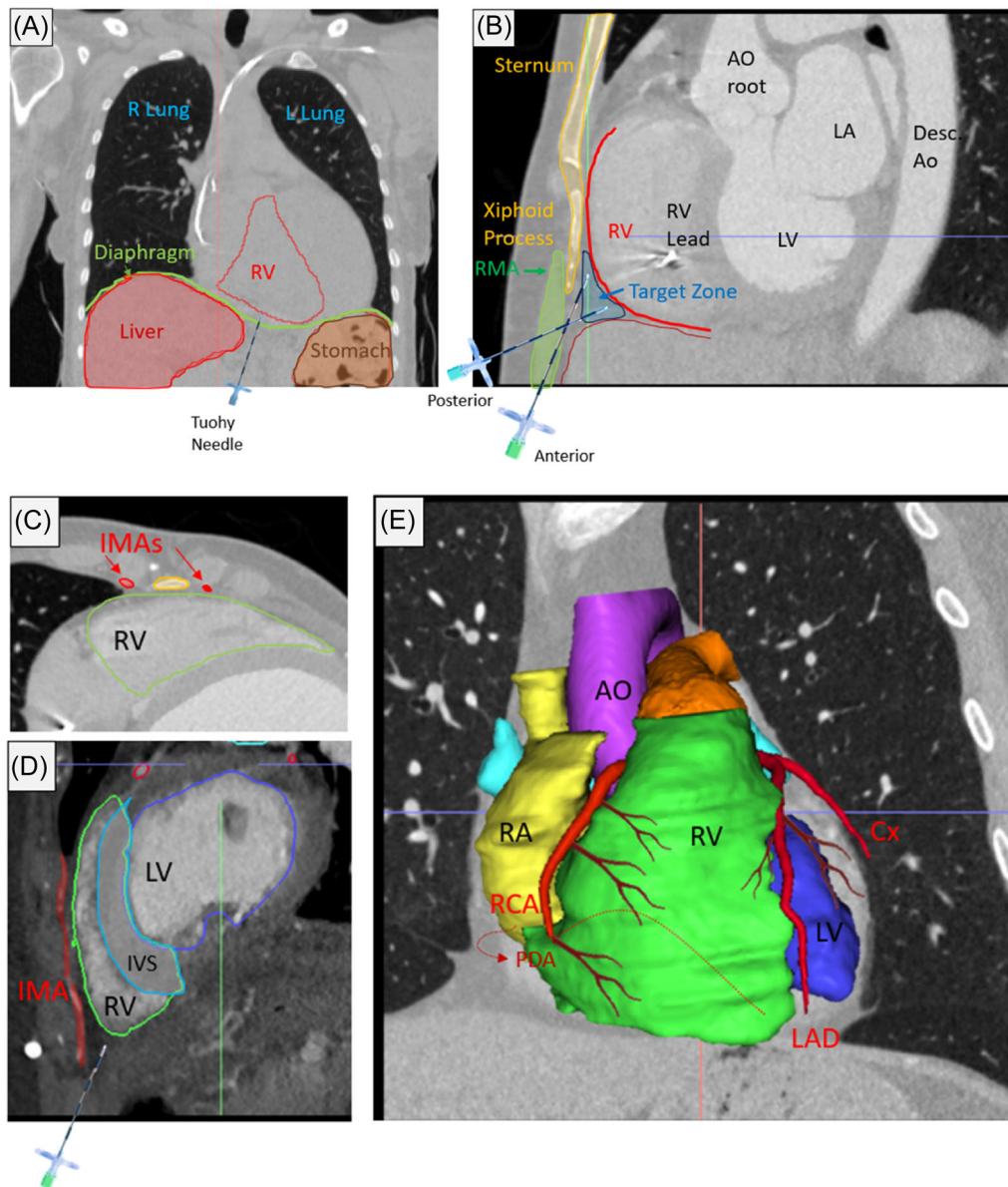


FIGURE 1 Overview of relevant anatomical structures for epicardial access. (A) Coronal CT chest view outlining the relationship of major abdominal (liver, stomach) and thoracic (lungs) organs and the heart when accessing the pericardial space from a subxiphoid position. Not shown is the transvers colon which in selected patients can be of concern for example, mega-colon in patients with Chagas disease. (B) CT sagittal view illustrating the Tuohy needle orientation puncturing through the rectus abdominis muscle (RA < M) to reach the space beneath the xiphoid process with a more vertically positioned needle to go anteriorly of the RV and more horizontal position to target for a posterior approach. (C and D) On the inside of the anterior chest wall the internal mammary artery (IMA) runs on the right and left to the sternum and coronary arteries are branching out on the surface of the heart and at risk of being lacerated. Equally important (but not shown) are abdominal subdiaphragmatic vessels including the superior epigastric artery, which may cause intrabdominal bleeding. (A–E) Preprocedural imaging with cardiac CT may provide important anatomical information to inform epicardial access approach.

Time requirements for access using MNPs alone or in a NiN approach have not been directly reported.

3.3 | Wire-guided pericardial puncture

Using the same setup as the traditional Sosa approach, the Tuohy needle is preloaded with a J wire and kept in the needle while

advancing from the subxiphoid puncture site towards the edge of the triangular space formed by the xiphoid process, RV apex, and dorsal surface of the diaphragm. The needle position is adjusted in RAO and the left lateral projection. The J wire is then advanced at this site until it will curve back upon reaching the fibrous layer of the pericardial and pulsations can be palpated. The wire is retracted and simultaneously advanced with the needle until resistance decreases and the wire “falls” into the pericardial space (see Figure 1C for

TABLE 1 Indications for epicardial access in cardiac electrophysiology.

Epicardial mapping and ablation for ventricular arrhythmias	<p><i>Indication depending on estimated likelihood of presence of functionally critical epicardial substrate based on imaging, etiology, VT-ECG, and previous ablation attempts (institutional protocols may vary):</i></p> <ul style="list-style-type: none"> • Nonischemic, arrhythmogenic, hypertrophic, or Chagas CMP with imaging suggesting subepicardial/mid myocardial substrate \pm12 lead VT ECG • Ischemic VT <ul style="list-style-type: none"> ○ Preprocedural: VT ECG suggesting epicardial exit, aneurysm, large transmural infarction ○ Intraprocedural: Incomplete diastolic pathway or “pseudofocal” endocardial activation pattern without prematurity on local EGM, no/minimal endocardial substrate to target, clinical VT remains inducible despite extensive endocardial ablation ○ Re-do following failed endocardial only approach <p><i>Patient characteristics precluding access of the endocardial chamber, for example:</i></p> <ul style="list-style-type: none"> • Mobile endocardial thrombus with risk of embolism • Mechanical valves precluding endocardial access
Epicardial mapping and ablation for supraventricular tachycardias and atrial arrhythmias	<ul style="list-style-type: none"> • Epicardial accessory pathway ablation following failed endocardial attempts • Sinus node modification • Emerging: Combined endo-epicardial ablations for persistent AF, failure of endocardial ablation to block linear lines (e.g., commonly roof or mitral isthmus line) due to suspected epicardial connections (e.g., septo-pulmonary bundle, vein of marshal)
Pericardial effusion/tamponade	<ul style="list-style-type: none"> • Iatrogenic pericardial tamponade complicating procedure
Phrenic nerve protection	<ul style="list-style-type: none"> • Endocardial target site with phrenic nerve capture for example, right atrial AT or in context of epicardial procedure
Left atrial appendage occlusion	<ul style="list-style-type: none"> • Nonsurgical, minimal invasive LAA occlusion in patients with contraindications to oral (or periprocedural) anticoagulation and elevated risk of stroke
Epicardial device therapy (PPM, CRT, ICD)	<ul style="list-style-type: none"> • Contraindications or failure for transvenous device (e.g., recurrent infectious or thromboembolic complications, limited venous access, congenital heart disease, mechanical tricuspid valve, recurrent lead failure, or displacement) • Contraindications or failure for subcutaneous ICD (e.g., failed screening, body habitus, requirement for brady or resynchronisation therapy, device, or lead failure)
<i>Investigational:</i> Intrapericardial antiarrhythmic pharmacological therapy	<ul style="list-style-type: none"> • Selective intrapericardial drug delivery to the target tissues to increase local tissue concentration and minimize systemic side effects (e.g., amiodarone,⁴ sotalol,⁵ flecainide⁶ • Long-term delivery with controlled drug release systems for example, drug eluting patch⁷ or miniaturized robotic devices performing in vivo semiautonomous epicardial injections⁸

illustration). A single center experience with this approach reported high success rates and lower complications when compare to the traditional contrast-guided puncture technique. Reported epicardial access time was very short— 5.34 ± 0.5 min.¹⁶

3.4 | SAFER approach: Sustained apnoea and right ventriculography

The most recent addition to proposed subxiphoidal percutaneous access techniques is termed the “SAFER” approach. This involves a combination of right ventriculography and epicardial puncture during sustained apnoea. A single tertiary center case series reports excellent success rate and low complication rates (no inadvertent RV punctures, one subdiaphragmatic/left superior epigastric artery injury managed with manual compression in a total of 105 patients). Time requirements were low—average 7 min (IQR 5–14 min).¹⁸ In centers, performing VT ablations routinely under general anaesthesia, the approach can be easily implemented in current workflows without extra equipment. This approach may be particularly useful in patients with right ventricular cardiomyopathies. In these patients, the right ventriculography could

provide important information delineating the dilated and/or aneurysmatic RV silhouette in relation to the access needle.

3.5 | Needle visualization and integration in the electro-anatomical mapping system

Real time visualization of the access needle in 3-dimensional space and its relation to the heart and surrounding organs may improve safety of the epicardial access. With electro-anatomical mapping systems (EAMS) allowing for integration of patient specific anatomical segmentations from preprocedural cardiac CTs more tailored access can be achieved. The needle and access path can be visualized within the EAMS by attaching sterile electrode clamps to the needle and connecting it via a jumper cable to the pinbox of the EP recording system. Even though promising, easy to implement and, in case of ablation procedures, no extra cost given the routine use of EAMS for ablation procedures, reported experience with this approach is limited to a small case single center case series of eight patients. Epicardial access was successful in all patients. One inadvertent RV puncture without need for intervention was reported.³⁵

TABLE 2 Overview percutaneous epicardial access techniques.

Method	Brief description	Publication	Center	Proc. Nr	Success rate ^a	Complicat. Rate ^b	Note ^c
1	Sosa approach Blunt Tip 17G epidural needle (Tuohy) inserted under fluoroscopy ± contrast injection	Della Bella et al. 2011 ⁵ Sacher et al. 2010 ⁹ Tung et al. 2013 ¹⁰ Santangeli et al. 2015 ⁸ Li et al. 2018 ³³ Mathew et al. 2021 ¹¹ Kumar et al. 2015 ¹⁴ Roberts-Thomson et al. 2010 ¹² Pisani et al. 2020 ¹³	Multicenter Multicenter Single center Single center Single center Single center Multicenter Single center	218 136 109 39 192 271 291 149	97.2% 90% 94% 100 98% 93.7% 94% 89.3%	4.1% 5% 8.8% 4% 11.6% 8.5% 11.3% 4.7%	
2	Microneedle Puncture (MNP) and Needle-in-Needle ("NIN") Long 21G Micro-puncture or spinal ("Chiba biopsy) needle inserted through short-large bore needle (17/18G) inserted under fluoroscopy ± contrast injection	Kumar et al. 2015 ¹⁴ Gunda et al. 2015 ¹⁵	Multicenter (all NIN) Multicenter (NIN if ↑ subcut tissue)	23 219	100% 100%	8.7% 1.4%	N = 2 peric. bleeding >80 mL
3	Wire guided access Tuohy Needle preloaded with J-Wire, J wire advanced until curving against the parietal pericardium, retracted, and needle and wire advanced simultaneously until wire "falls" in pericardial space	Long et al. 2020 ¹⁶	Single center	41	97.6%	4.7%	N = 1 pericardial effusion, N = 1 tamponade
4	SAFER approach General Anaesthesia, RV ventriculogram with power injector in AP, and LL in end expiratory apnoea, needle trajectory defined in AP and puncture during end expiratory apnoea in LL with RV ventriculogram as image overlay	Romero J et al. 2023 ¹⁷	Single center	105	100%	0.9%	N = 1 subdia-phragmatic/left superior epicardic artery injury. Managed with manual compression.
5	EAMS-integration EAMS-RV map ± CT fusion. Tuohy needle attached to sterile electrode clamps and connected to pinbox, tip of need used electrode, mapping points taken during advancement of needle.	Bradfield et al. 2013 ¹⁸	Single center	8	100%	12%	N = 1 RV puncture
6	EpiAccess™ Access needle tip embedded with a pressure sensor for real time report of pressure	Di Biase et al. 2017 ¹⁹	Multicenter	25	100%	4%	N = 1 delayed pericardial effusion

(Continues)

TABLE 2 (Continued)

Method	Brief description	Publication	Center	Proc. Nr	Success rate ^a	Complicat. Rate ^b	Note ^c
pressure-frequency sensor needle	waveform while advancing needle towards pericardial space						
7	ViaOne™; Blunt-Tip concealed needle device (BTCND) A telescopic tube feature a rotatable serrated disc at its distal end to capture the parietal pericardium, grasper pull the pericardium away from the heart, needle remains concealed inside the tube while guidewire is advanced to pericardial space	Derejko et al. 2022 ²⁰	Single center	11	91%	0%	No access related complication
8	CO ₂ -insufflation Intentional perforation of RAA or CS branch into pericardial space with 0.014–0.018 in guidewire and CO ₂ insufflation over 2, 4 Fr microcatheter, subxiphoidal puncture under left lateral fluoroscopy	Greenbaum et al. 2015 ²¹ Silberbauer et al. 2017 ²² Julia et al. 2021 ²³ Foo et al. 2023 ²⁴	Single center Single center Multicenter Single center	11 12 102 5	85% 92% 96.1% 100%	0% 8.3% 4.9% 20%	No access related complication N = 1 bleeding >150 mL N = 5 significant bleeding >80 mL N = 1 CO ₂ injection to RV and inadvertent RV puncture No access related complication
9	Laparoscopic guided approach Trocar in umbilical scar, optic laparoscope insertion in peritoneal cavity, epicardial puncture via subxiphoid approach under direct visualization	Cerantola et al. 2023 ²⁵ Carmo et al. 2020 ²⁶	Single center Single center	6 11	83% 100%	0% (18% ^a not directly access related)	No access related complication N = 1 cardio-genic shock, N = 1 phrenic nerve palsy
10	Closed pericardio-stomy Mini subxiphoid incision with pericardiostomy via vertical incision. Two separate percutaneous punctures left and right to incision using Seidinger technique but entering under direct visualization through window. Wires and drain inserted over puncture site, subxiphoid incision closed before starting to map	Burg et al. 2023 ²⁷	Single center	4	100%	0%	No access related complication
Preclinical techniques							
11	Percut. Videoscopy Dedicated videoscope and tool-kit for single access percutaneous puncture, 14G access needle for puncture and CO ₂ insufflation into thoracic space, pericardial	Opfermann et al. 2023 ²⁸	Precinical (pigs)	6	100%	0%	

TABLE 2 (Continued)

Method	Brief description	Publication	Center	Proc. Nr	Success rate ^a	Complicat. Rate ^b	Note ^c
12	CT guided pericardial RF needle access access with needle with embedded micro-camera for direct visualization	Ludwig et al. 2015 ²⁹	Preclinical (pigs)	5	100%	0%	Spatial inaccuracy 4.2 ± 2.2 mm
13	Transvenous puncture sites Direct RAA Puncture and perforation with exit via 8Fr sheath Direct transvenous RV puncture and exit with 6 Fr sheath	Scanavacca et al. 2011 ³⁰ Qin et al. 2022 ³¹	Preclinical (pigs) Preclinical (pigs, beagles)	17 17	100% 100%	12% 6%	N = 2 major bleeding with tamponade N = 1 significant bleeding

^aSuccess defined as pericardial access including subsequent mapping/ablation.

^bSignificant epicardial access related complications only, including significant bleeding defined as >80 mL.

^cComplications specified for case series with small numbers due to high relative contribution to complication rate—For detailed list of complications in all studies see Supporting Information: Table 1.

^dIncluding patients with pericardial adhesions, re-do epicardial access and previous cardiac surgery, overall success for epicardial access calculated from described failed attempts in subgroups.

3.6 | EpiAccess™ system with real-time pressure sensor

While maintaining the general procedural setup and approach of the original puncture technique, the employed access needle contains a pressure-frequency fiber optic sensor within a stainless tube (EpiAccess System™, by EpiEP, Inc., see Figure 3A,B). This allows display of real time pressure frequency signals from the sensor while the needle is advanced towards the pericardial space. The needle is otherwise similar in shape, size, and handling to the Tuohy needle. Following the first pilot studies with encouraging results,^{19,36} a multicentre study involving 25 patients achieved successful epicardial access in all patients with only one delayed pericardial tamponade, which was not clearly related to the epicardial access.³⁷ Time requirement and costs of the proposed setup and device have not been reported in detail.

3.7 | Blunt tip concealed needle device (BTCND): ViaOne™ device (CardioVia)

In 2009 the first patent for a pericardial access tool using a tube with elongating structures that pierce the parietal pericardium when in contact and by retracting separating out the pericardial layers, has been proposed. The retraction of the parietal layer opens up the pericardial space to then safely puncture and introduce the guidewire without the need to push the device forward to the heart and risk inadvertent RV puncture²⁰ The concept has been evolved into a complete operating system undergoing regulatory approvals from FDA and CE. In 2022 the first results of the single center in-human feasibility and safety study of this “blunt-tip, concealed needle device (BTCND)” (ViaOne, CardioVia, see Figure 3C) for pericardial access have been published. Epicardial access was successful in 10 out of 11 patients with no significant complications reported.³⁸ The results of this single center feasibility study are encouraging and are awaiting further validation in a larger population. Time requirement and expected cost of the device were not specified.

3.8 | Pericardial carbon dioxide insufflation via intentional RAA or CS exit

With a similar rationale, separating the epicardial and pericardial layers to facilitate the subxiphoid puncture and minimize the risk of inadvertent RV perforation or coronary laceration, pericardial carbon dioxide insufflation over small microcatheters (2.8 Fr, see Figure 3D) following intentional RAA perforation has been suggested. Feasibility studies in porcine models confirmed good hemodynamic tolerance and no or only small bleeding even if performed under full anticoagulation.²¹ First in human case series used the right atrial appendage exit²² and a later modification suggests exiting a coronary sinus branch.²⁴ Both

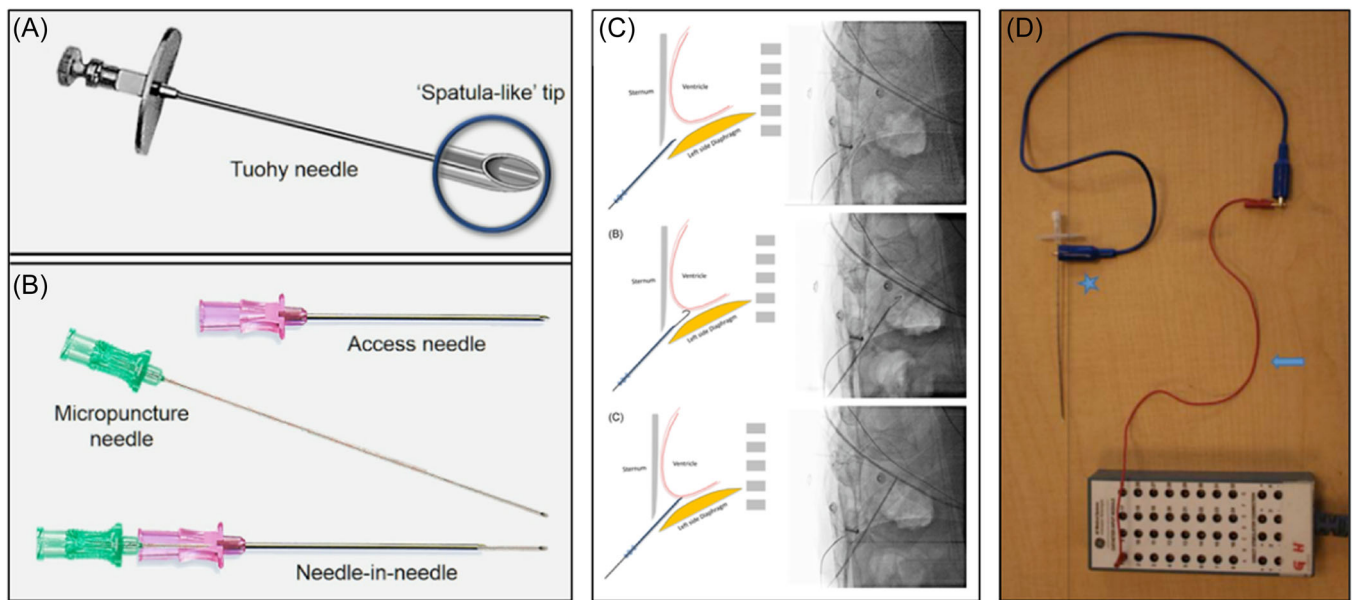


FIGURE 2 Variation of the Sosa approach using standard Catheter Lab equipment. (A): Traditional Tuohy needle compared to (B) Micropuncture needle (green) and “needle-in-needle” approach (reprinted from Aryana et al.³² with permission of the publisher Elsevier, Licence Nr 5563600663709) (C) schematic procedural steps of wire guided pericardial puncture with corresponding fluoroscopy images on right (for details see text, reprinted from Long et al.¹⁶ with permission of the publisher John Wiley and Sons, Licence Nr 5563601291719). (D) Setup for connecting the epicardial access needle over alligator clips (blue) and jumper cable (red) to the EP recording system pinbox to integrate the access needle in the EAMS system. (reprinted from Bradfield et al.¹⁸ with permission of the publisher John Wiley and Sons, Licence Nr.5563600962189).

variations report equally high success rates. Micro-needles with preloaded wires have been recommended instead of traditional large bore needles due to the risk of rapid CO₂ deflation and RV recoil towards the needle. Bleeding may occur, though so far no cases requiring surgical intervention have been reported. Coronary sinus perforations may occasionally result in intramyocardial wire tracking which, if unrecognized, has been reported to result in inadvertent CO₂ insufflation in the ventricular cavity.²⁵ Case series using a CS exit report comparatively long access times of 28 ± 12 min,²⁴ 37 ± 17.5 min²⁵ and 16–30 min³⁹ though operator learning curves and future refinement in the access technique may improve time efficiency. The technique may be somewhat less suitable for patients with known difficult CS anatomy for example, from prior CRT device insertion procedures or recent CRT device implants with concerns for lead displacement as well as the general concern of infection in case of prolonged manipulation in direct contact with the permanent lead. Alternative exit sites including the right atrial appendage could be considered in these situations.

3.9 | Laparoscopic guided epicardial access

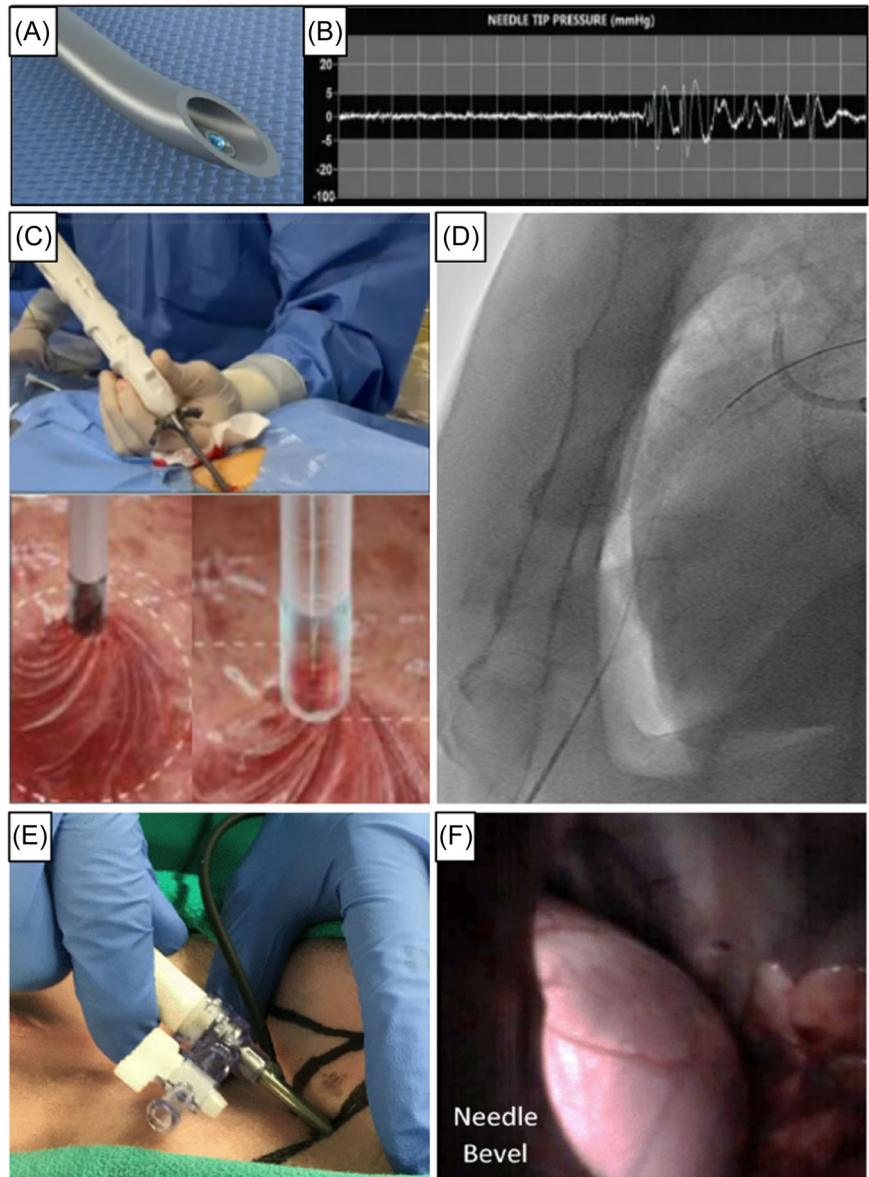
This is proposed for patients with Chagas disease and mega-colon and/or hepatomegaly with high risk of abdominal organ injury during traditional subxiphoidal puncture,²⁶ feasibility and safety of a laparoscopic approach has been tested. Following insertion of a trocar in the umbilical region and introduction of the optic

laparoscope a percutaneous subxiphoidal epicardial puncture, either by standard or micro-needle, is performed under direct visualization to prevent inadvertent organ damage. Following successful access of the pericardial space, the laparoscopic trocars can be retracted and port sites closed as per routine surgical practice (either by suture or with dedicated port closure equipment). The remaining pericardial access site is equivalent to standard percutaneous puncture sites and as such do not require a surgical closure. Experience is still limited and only a small single center case series has been reported. Epicardial access was successful in all patients. One patient suffered a peri-procedural cardiogenic shock and one patient phrenic nerve palsy. There were no direct access related complications.²⁷

3.10 | Closed pericardiostomy technique

The closed pericardiostomy technique is a recently proposed hybrid approach in collaboration with the cardiac surgeons to gain access under direct visualization to minimize risk of extracardiac injury during entry as well as allows to separate pericardial layers before puncture to minimize the risk of cardiac injury. The surgical involvement is limited to the time of access and thereafter a routine percutaneous epicardial procedure is pursued. The technique has been described in detail in a small case series of four patients with successful access in all of them and no access related complications. Mean time from skin incision to pericardial wire/drain insertion was 18.5 min, mean time from skin incision to initiation of mapping was 27 ± 6 min.⁴⁰

FIGURE 3 Dedicated percutaneous epicardial access tools (A and B) EpiAccess™ needle with a distal tip fiber optic sensor. Exemplary tracing showing the needle tip pressure change once the pericardial space has been entered. (reprinted from Di Biase et al.¹⁹ with permission of the publisher Elsevier, Licence Nr 5563610658252) (C) ViaOne™ Device for subxiphoidal puncture, the device allows to grasp the tissue of the parietal pericardial and retract it. Subsequently the concealed needle inside is able to puncture and a guidewire can be advanced (reprinted from Derejko et al.²⁰ with permission of the publisher Elsevier, Licence Nr 5563610906104). (D) Carbon dioxide insufflation and puncture in left lateral view. The carbon dioxide creates a larger separation between epi and pericardial layer to minimize the risk of inadvertent RV or coronary artery puncture (reprinted from Greenbaum et al.²¹ with permission of the publisher Elsevier, Licence Nr 5563620247031) (E and F) Videoscope Subxiphoidal puncture with 15G needle with connector for CO₂ insufflation in thoracic space and entry of dedicated needle tool with embedded micro-camera allowing to directly visualize the heart for subsequent puncture (reprinted from Opfermann et al.²⁸ published under Creative Commons CC BY licence).



In brief, a surgical small subxiphoidal vertical incision and dissection down to the preperitoneal fat is performed without entering the peritoneal space. The cardiophrenic fat pad is exposed and the fibrous pericardium exposed and with two sutures anchored to the lower edge of the incision to pull the heart and diaphragm downward. The parietal pericardium is then tented of the heart and a vertical incision performed to visualise the epicardial surface. Thereafter, two separate percutaneous punctures are made into the pericardial space at the right and left sternocostal angle on either side of the subxiphoid incision using standard Seldinger technique and a wire and drain inserted into the epicardial space under direct visualization through the window. Position is confirmed under fluoroscopy and if no complications identified, the pericardial window closed and further mapping performed as usual through the percutaneously inserted access sites.

4 | FUTURE EPICARDIAL ACCESS AND MAPPING TECHNIQUES: PRECLINICAL AND EMERGING STRATEGIES

4.1 | Percutaneous subxiphoidal videoscope

To allow for epicardial access under direct visualization, a minimal invasive multilumen tool with deflectable endoscope has been proposed,²⁸ and employed in animal studies for implantation of pacemaker and ICD leads. To minimize the entry size of the device, facilitate the process and obviate the need to coordinate two working channels to maintain visualization of the access tool, a subsequent percutaneous pericardial tool kit using a Veress needle (14G) has been developed. The micro CMOS camera (complementary metal oxide semiconductor) is directly embedded in the needle. In a

pig-animal study this was successfully employed for gaining epicardial access under direct visualization (see Figure 2E,F).²⁹ No human studies have been reported to date.

4.2 | CT guided pericardial RF needle access

A preoperative CT is acquired to reconstruct patient individual anatomy and subsequent integration in a dedicated virtual imaging platform. A 0.036 inch needle with electrical insulation except for two small surfaces recessed from the tip, is co-registered with the CT and visualised in the imaging system in real time. For pericardial access, the RF needle is advanced under visualization on the imaging system and once in situ, RF energy is delivered through the exposed surfaces on the needle tip to perforate through the pericardial layer. Spatial inaccuracy was 4.4 ± 2.2 mm between target and actual puncture site.³⁰

4.3 | Transvenous percutaneous epicardial access strategies

Intentional right atrial puncture and exit with a 8 Fr sheaths to directly introduce an ablation catheter into the epicardial space has been successfully tested in a larger animal study. Epicardial access was achieved in all animals with 2/17 developing cardiac tamponade.³¹

Intentional right ventricular exit has equally been proposed and tested in preclinical animal studies Successful exit was achieved in all 17 animals using a 0.014 PTCA guidewire and 1.8 Fr microcatheter. To assess the haemostatic ability of the RV, the puncture site was dilated up to a maximum of 3.0×23 mm balloons for 15 min or 6 Fr catheters for up to 3 days. While a pericardial effusion without tamponade was observed following dilatation with the 3 mm balloon, none were observed with the 2.5 mm balloons demonstrating the ability of the right sided cavity to seal even comparatively large puncture sites⁴¹ and potentially could be use as a rapid easily accessible exit site for microcatheters for example, for carbon dioxide insufflation.

4.4 | Epicardial ICD lead placement approaches

With the recognition of endovascular pacemaker and ICD lead complications there has been a drive to implant extravascular lead systems. Traditional epicardial defibrillation patches have been largely abandoned and replaced by off-label use of subcutaneous and transvenous coils inserted in the epicardial space. Despite the formally appealing combination of entirely extravascular device configuration providing tachy-, brady, and resynchronisation therapy as indicated, high epicardial lead failure rates remain a concern.⁴² In turn, the success of the subcutaneous ICD has driven innovation in subxiphisternal ICD lead placement to not only facilitate low energy

shock therapy but also enable epicardial overdrive and bradycardia pacing. Implantation technique requires preoperative imaging to assess the substernal space to determine whether the tunneling tool needs adjustment to the anatomy and inform the angle of insertion. Using a specially designed trochar combined with X-ray screening and digital dissection minimizes the risk of ventricular perforation with a good safety profile.⁴³ Other strategies are evolving using similar techniques to deliver smaller ICD leads and combine these with standard ICD generators. Challenges remain in ensuring optimal sensing and lead stability.

4.5 | Robotic-assisted epicardial mapping and ablation

To overcome existing shortcomings in electro-anatomical mapping and ablation technologies, miniaturized mobile epicardial robotic walkers able to navigate on the epicardial surface, map, and deliver precise controlled saline enhance RF needle ablation have been proposed.⁴⁴

The HeartLanderTM, is a small flexible probe (width 8 mm, height 5.5 mm) that could be inserted minimally invasively over subxiphoid access. The "feet" of the walker adhere to the epicardial surface with suction. By alternating application of suction and pushing and pulling on flexible nitinol push wires locomotion is achieved, which is additionally synchronized to the heart beat and respiratory movement via a chest mounted accelerometer.⁴⁵ Feasibility of mapping has been demonstrated first in artificial heart models and the porcine in vivo models. Targets were located within 2 mm using the single equivalent moving dipole mapping (SEMDM) technique. Feasibility of ablation via needle insertion was assess in an artificial tissue model and ex vivo tissue and within 2 mm of the target depth.⁴⁶ Further studies showed that doppler ultrasound signals were successfully used to identify and avoid coronary vascular during cardiac interventions using the robotic device.⁴⁷ Robotic assisted percutaneous pericardial access has not yet been shown to be feasible.

The CardioARMTM (Medrobotics) is an alternative "Snake robot" that has been successfully employed in in vivo animal as well as a small case series of three human undergoing hybrid endo epicardial VT ablations over a single port pericardial access (subxiphoid window).⁴⁸ No larger case series have been reported.

5 | CONCLUSION

Electro-anatomical mapping and ablation technology is certain to undergo further substantial and potentially revolutionary transformation in the near future with multiple new technologies on the horizon, including robotics. Any form of direct, invasive interventional therapy will require access to the heart in one way or another. Improvement of epicardial access approaches is therefore crucial and innovative strategies have been proposed over the years to overcome existing challenges and facilitate a more widespread

utilization. Yet many of these approaches have only been tested in a limited number of patients and centers and awaiting validation in larger populations. Standard institutional approaches may vary and the first-line approach is dictated by local expertise, available equipment and on-site cardiothoracic surgical service. An unequivocally superior "all-in-one" safe, efficient, low cost and quick strategy has yet to be proposed.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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