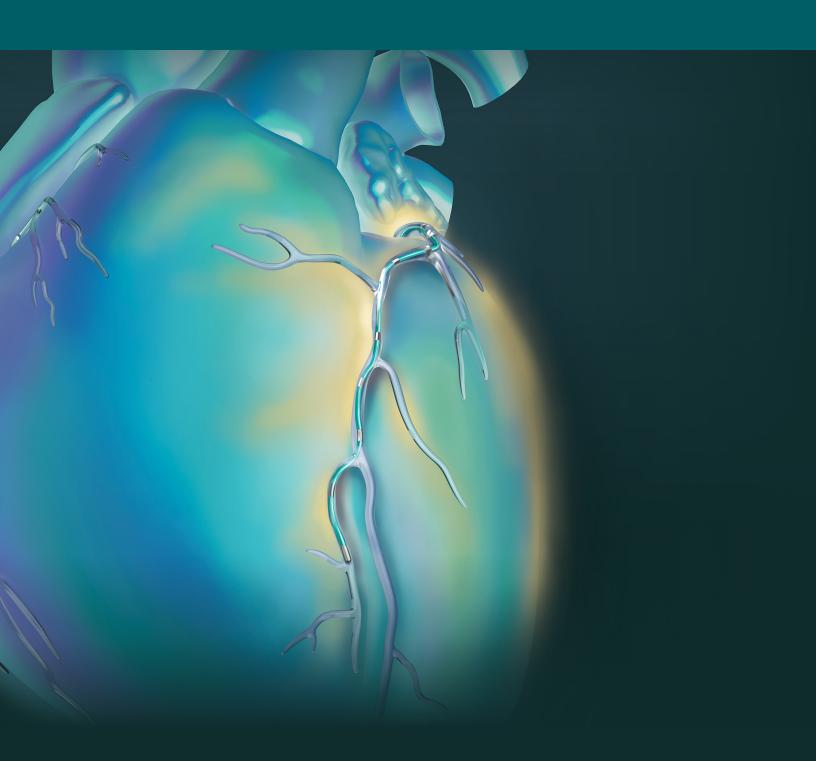




Mapping Idiopathic Ventricular Arrhythmias Published Literature and Techniques



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Background | Coronary sinus anatomy

The coronary sinus (CS) is the largest coronary vein and forms a crown-like structure between the left ventricle and left atrium on the posterior side of the heart. This vein originates from the coalescence of the great cardiac vein (GCV) and the oblique vein of Marshall (VOM) (Figure 1)¹.

The coronary venous network (Figure 1) is a collection of venous tributaries including the CS, GCV, oblique VOM, posterior vein of the left ventricle, anterior interventricular vein (AIV), middle cardiac vein (MCV), and small cardiac vein^{2,3}. This network drains deoxygenated blood from the myocardium into the right atrium through the CS, making it a critical access route for mapping and ablating various ventricular arrhythmias¹.

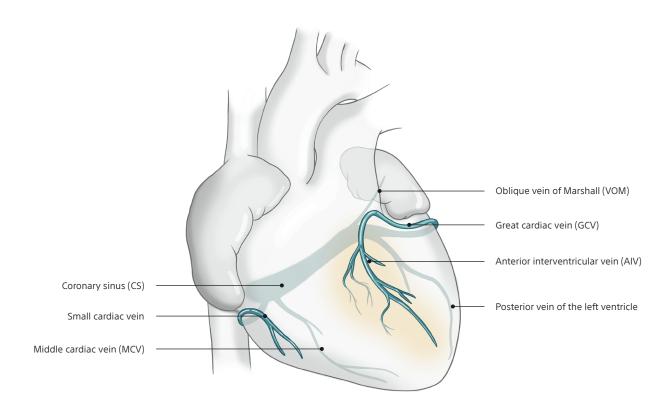


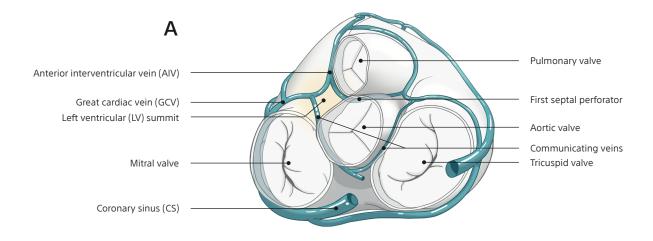
Figure 1. Coronary venous mapping provides an alternate access route for deep mapping and ablation of epicardial and intramural sites when treating complex arrhythmias (such as idiopathic ventricular arrhythmia).

Background | Overview of idiopathic ventricular arrhythmias

Idiopathic ventricular arrhythmias (I-VAs) include both ventricular tachycardias (VTs) and premature ventricular contractions (PVCs), but the underlying mechanisms are not associated with a myocardial scar^{4,5}. I-VAs are commonly observed in patients without any structural heart disease but can also occur in patients with structural heart disease⁴.

I-VAs typically originate from the ventricular outflow tracts, with greater prevalence from the right ventricular outflow tract (RVOT) than the left ventricular outflow tract (LVOT). In the RVOT, I-VAs often originate at the interventricular septum (IVS), while in the LVOT they originate at the aortic root or under the aortic sinus cusps^{6,7}. Other major sites of origin for I-VA include the left ventricular (LV) summit (Figure 2A), left or right coronary cusps (i.e., cusp VT), mitral annulus (MA), papillary muscle, aortic valve, and pulmonary valve⁸. These origin sites can be epicardial, endocardial, or intramural (Figure 2B).

Catheter ablation is the preferred option for treating I-VA. However, mapping and ablating I-VAs that originate from the LV summit and IVS remains challenging despite significant methodological and technological advances⁹. The thick myocardium in this region makes intramural origin sites largely inaccessible to endocardial and epicardial mapping^{5,9,10}. As such, direct recording of intramural substrates requires catheter insertion deep within the septal coronary venous tributaries (Figure 2)¹¹. This coronary venous mapping approach enables precise substrate identification and characterization to help guide the ablation of intramural septal VAs (especially for patients with prior failed ablations).



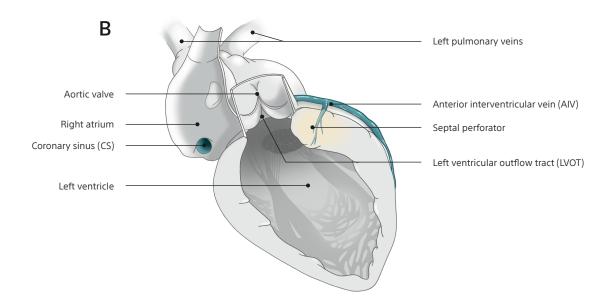


Figure 2. A) Communicating veins that branch off from the GCV can provide epicardial access to I-VA origin sites in the LV summit via the CS. B) Septal perforators that penetrate the myocardium at the LV summit can allow for more direct recording of intramural substrates.

Key publications on idiopathic ventricular arrhythmias

Outflow tract ventricular arrhythmias

Successful Treatment of Idiopathic Left Ventricular Outflow Tract Tachycardia by Catheter Ablation or Minimally Invasive Surgical Cryoablation

Frey et al. Pacing and Clinical Electrophysiology, 2000¹².

Study Overview

Condition: Idiopathic LVOT tachycardia

Procedure: Radiofrequency (RF) ablation or minimally invasive surgical cryoablation

Epicardial and endocardial mapping identified the precise site of VA origin in three patients with LVOT tachycardia. The epicardial LV was mapped with a 2.3F 16-pole small mapping wire (Pathfinder® catheter, Cardima) inserted into the AIV via the CS and GCV. The endocardial LV was mapped, and subsequently ablated, with a quadripolar 4-mm tip catheter (Cordis Webster) advanced retrograde into the LV via the right femoral artery. VT ablation was successful in all three patients using RF for endocardial sites or cryoablation for epicardial sites.

- Pace-mapping successfully identified appropriate ablation sites for LVOT I-VAs.
- Two patients had earliest ventricular activation recorded from the endocardial LVOT (at an anterolateral and an anterior site, respectively) and endocardial catheter ablation was successful in both cases.
- In one patient, VT was recorded from an epicardial LVOT site, but RF ablation was unsuccessful from the endocardial site. The VT was treated at the epicardial target region with minimally invasive surgical cryoablation instead.
- Though epicardial LV mapping via the CS is a useful adjunct to endocardial VT mapping, epicardial ablation carries risks of acute coronary venous and arterial injury.
- Successful idiopathic LVOT tachycardia ablation and earliest origin site identification may require both endocardial and epicardial (coronary venous) mapping.

Key publications on idiopathic ventricular arrhythmias

Outflow tract ventricular arrhythmias

Simultaneous Mapping in the Left Sinus of Valsalva and Coronary Venous System Predicts Successful Catheter Ablation from the Left Sinus of Valsalva

Ito et al. Pacing and Clinical Electrophysiology, 2005¹³.

Study Overview

Condition: Idiopathic VT or PVC

Procedure: RF ablation from the left sinus of Valsalva (LSV)

RF ablation was performed on patients (n=25) with symptomatic idiopathic VT or PVCs originating from the left epicardium (Epi-VT). In all cases, earliest ventricular activation was detected in the LSV or GCV-AIV. Simultaneous mapping was performed in the LSV and coronary venous system (CVS) using a 7F quadripolar catheter (Biosense Webster) and 2F octopolar mapping catheter (Pathfinder® catheter, Cardima), respectively. The goal was to compare the earliness of activation in the LSV (VA[LSV]) and GCV-AIV (VA[GCV-AIV]) between patients with successful (n=17) versus failed (n=8) RF application from the LSV to assess how well LSV and GCV-AIV electrograms can predict RF ablation efficacy.

- This study has reported a unique RF ablation prediction method based on the analysis carried out in successful vs. unsuccessful cases.
- The result of the calculated formula, VA[GCV-AIV] VA[LSV] (difference in earliness of activation between the LSV and GCV-AIV) depended on the tachycardia origin site (Table 1).

Origin of VT		VA[GCV-AIV] – VA[LSV]
Between the LSV and GCV-AIV	Closer to the LSV	< 0 ms
	Closer to the GCV-AIV	> 0 ms
Distant from the LSV	Closer to the GCV-AIV	≥ 10 ms

Table 1. The relationship between VT origin site and difference in earliness of activation between the LSV and GCV-AIV.

- RF catheter ablation from the LSV was successful if the result was VA[GCV-AIV]- VA[LSV] < 10 ms.
- Increased distance from the LSV may result in failure of RF catheter ablation for Epi-VT.
- VA earliness of activation between the GCV-AIV and LSV can predict successful RF catheter ablation from the LSV.

Key publications on idiopathic ventricular arrhythmias

Outflow tract ventricular arrhythmias

Idiopathic Epicardial Left Ventricular Tachycardia Originating Remote from the Sinus of Valsalva

Daniels et al. Circulation, 2006¹⁴.

Study Overview

Condition: Idiopathic VT originating from perivascular sites on the LV epicardium

Procedure: Mapping and RF ablation or cryoablation via the CVS*

Ablation was performed on 12 patients (8 women, 4 men; mean age: 44 ±21 years) with epicardial idiopathic VT originating remote (over 10 mm) from the aortic sinus of Valsalva (ASOV). Two multipolar catheters were positioned in the right atrium and/or right ventricle for pacing and recording the idiopathic VT. A small 2.5F 16-pole microwire (Pathfinder® catheter, Cardima) was initially positioned along the distal GCV and proximal AlV in the CVS. Subsequently, the 2.5F catheter or a smaller 1.5F 8-pole catheter (Pathfinder® catheter, Cardima), was moved to other areas of the CVS for mapping, as directed by the electrocardiogram (ECG) recordings and endocardial mapping findings. ECG recordings were analyzed digitally to compare epicardial vs. other VT origin sites. Ablation was successful in nine patients via the CVS or percutaneous transpericardial catheterization, though two patients required direct surgical ablation due to anatomic constraints.

- CVS mapping showed that epicardial activation preceded endocardial activation by >10 ms and should be considered early when evaluating epicardial idiopathic VT.
- The maximum deflection index (MDI) derived from a 12-lead ECG can help identify the precise site of epicardial idiopathic VT remote from the ASOV.
- Epicardial pace maps obtained from the CVS were a better match than endocardial pace maps, which resulted in more successful epicardial ablation procedures.

^{*}Note: Percutaneous transpericardial catheterization was used if the venous approach was not successful or if the ablation catheter could not be advanced to the earliest site of venous activation.

Key publications on idiopathic ventricular arrhythmiasOutflow tract ventricular arrhythmias

Successful Catheter Ablation of Left Ventricular Epicardial Tachycardia Originating from the Great Cardiac Vein

Kaseno et al. Circulation, 2007¹⁵.

Study Overview

Condition: Symptomatic, drug-refractory VT and PVC

Procedure: RF ablation

A 30-yr old patient underwent a second session of RF ablation (within the GCV) to relieve symptomatic, drug-refractory VT and PVC three years after an initial ablation. A 2F octopolar electrode catheter (Pathfinder® catheter, Cardima) was positioned in the transitional area from the distal portion of the GCV to the proximal portion of the AIV. The body of the electrode catheter had an acute bend at the anterobasal portion of the heart in left anterior oblique (LAO) projection. A 7F quadripolar catheter (Celsius® Catheter, Biosense Webster) was used to map and ablate in the LVOT endocardium and LSV, which eliminated clinical VT but not PVC. A 5F deflectable catheter (Ablaze®, Japan Lifeline) was used to map the GCV and target the local ventricular activation site for RF ablation. RF energy was gradually increased from 5W to 17W for 60s to successfully eliminate the VT and PVC.

- Detailed assessment of ECG and CVS recordings may help differentiate between VT arising from the LV epicardium versus the LSV.
- RF ablation within the CVS may be an alternative when the earliest ventricular activation is recorded
 within epicardial sites, and complete elimination of VT cannot be achieved with ablation at the
 LVOT endocardium or LSV. However, this approach may lead to complications including intramural
 thrombosis, cardiac tamponade, coronary artery injury and should only be attempted if ablation at
 the LVOT endocardium or LSV fails.

Key publications on idiopathic ventricular arrhythmias Summit ventricular arrhythmias

Idiopathic Ventricular Arrhythmias Originating from the Vicinity of the Communicating Vein of Cardiac Venous Systems at the Left Ventricular Summit

Komatsu et al. Circulation: Arrhythmia and Electrophysiology, 2018¹⁶.

Study Overview

Condition: Idiopathic VA originating from the LV summit

Procedure: RF ablation

LV summit mapping was performed in 14 patients with VA originating from the summit communicating veins (summit CV) and 17 patients with VA originating from the RVOT and aortic cusps. A small 2F microcatheter (EPstar Fix*, Japan Lifeline) was introduced through the lumen of a 6F decapolar catheter (Inquiry™ Luma-Cath™ Fixed Diagnostic Catheter, Abbott) and advanced into the CS between the aortic and pulmonary annuli for direct monitoring of the communicating vein. This mapping was used as a landmark for ablation from nearby endocardial structures.

- The myocardium near the summit CV may be a potential source of I-VA and is a challenging ablation site.
- Direct monitoring of the summit CV with a small multipolar catheter helped identify the precise site of VA origin and facilitated ablation through alternative adjacent sites.

^{*}Note: EPstar Fix (Japan Lifeline) is marketed as EPstar Fixed Electrophysiology Catheter (Baylis Medical) in North America. Baylis Medical Company is a wholly owned subsidiary of Boston Scientific Corporation.

Key publications on idiopathic ventricular arrhythmias Summit ventricular arrhythmias

A Novel Approach to Mapping and Ablation of Septal Outflow Tract Ventricular Arrhythmias – Insights from Multipolar Intraseptal Recordings

Pothineni et al. Heart Rhythm, 20219.

Study Overview

Condition: Septal outflow tract idiopathic VA

Procedure: RF ablation

This study reported a novel intramural mapping method that uses multiple bipolar recordings to identify the precise site of challenging VA (such as the LV summit and IVS). A detailed setup for the initial mapping procedure was described in four unique cases using a medium-curl steerable sheath (SureFlex™ Steerable Guiding Sheath, Baylis Medical* or Agilis™ NxT steerable introducer, Abbott) advanced over a guidewire to the distal CS and placed over the valve of Vieussens. A 2F octapolar mapping catheter (EPstar Fix† 2F; Japan Lifeline) was used to obtain activation information from various sites within the CVS and to perform selective septal perforator activation mapping in the septal LV (see Section 3.1 – Techniques). In some cases, a second 4F decapolar mapping catheter (EP Map-iT®, Access Point Technologies) was used to obtain simultaneous epicardial recordings. Both small mapping catheters were advanced through the same steerable sheath during the procedure. After systemic anticoagulation with intravenous heparin, LV endocardial activation mapping was performed using high density mapping catheters (HD grid, Abbott). Optimal ablation strategies were then designed based on the activation pattern (endocardial, intramural, or subepicardial) and propagation mapping.

- Insulated wires (VisionWire, Biotronik) can be used for septal coronary venous mapping. However, these wires only allow unipolar signals, which can be affected by far-field interference from anisotropic scar tissue¹¹.
- Subepicardial and intramural activation/propagation mapping can be achieved using multipolar catheters via the GCV-AIV and septal perforator veins, respectively.
- This novel mapping strategy involving multiple small multipolar catheters in the CVS facilitated 3D septal substrate characterization and, in conjunction with endocardial mapping, precise VA origin site localization for RF ablation.

^{*}Baylis Medical Company is a wholly owned subsidiary of Boston Scientific Corporation.
†Note: EPstar Fix (Japan Lifeline) is marketed as EPstar Fixed Electrophysiology Catheter (Baylis Medical) in North America.

Key publications on idiopathic ventricular arrhythmias Summit ventricular arrhythmias

Bipolar Radiofrequency Ablation of Septal Ventricular Tachycardia Facilitated by an Intramural Catheter

Waight et al. JACC Case Reports, 202117.

Study Overview

Condition: Intramural septal scar-related VT

Procedure: Bipolar RF ablation

This study describes the use of a 2F octapolar catheter (EPstar Fixed Electrophysiology catheter, Baylis Medical*) in treating scar-related septal VT in a 79-year-old woman. A 6F multipurpose catheter was advanced through a steerable sheath (Agilis™ NxT steerable sheath introducer, Abbott) to the junction of GCV-AIV to facilitate a venogram of the distal CS. The 2F octapolar catheter was then advanced into the summit CV in the region of the basal septal scar to measure fractionated and delayed potentials during sinus rhythm. The 2F EPstar intraseptal catheter revealed diastolic potentials when monomorphic non-sustained VT was induced. These diastolic signals, along with a history of failed unipolar ablations, justified a bipolar RF ablation strategy. RF was delivered to the septum region between a TactiCath™ SE catheter (Abbott) on the basal septum of the LV and a Thermocool® SF catheter (Biosense Webster) on the opposing right ventricular septal surface. The Thermocool® SF catheter served as the ground electrode. Pacing from the 2F catheter at high output was used to assess ablation success.

- The 2F octapolar catheter facilitated direct mid-wall electrogram sampling, which allowed accurate substrate localization.
- Accessing the summit CV facilitated:
 - Direct recording of abnormal potentials in sinus rhythm.
 - Recording of (otherwise easily missed) diastolic activity during brief non-sustained VT.
 - Intraseptal pacing to confirm substrate ablation.
- In cases with failed unipolar RF ablation for septal VT in the presence of intramural scar, bipolar RF ablation can provide an effective alternative¹⁸.
- Insufficient septal thickness, indicated by an intercatheter distance of <5 mm, was the only anatomic limitation to bipolar RF ablation in the presence of intramural scar¹⁹.

^{*}Baylis Medical Company is a wholly owned subsidiary of Boston Scientific Corporation.

Key publications on idiopathic ventricular arrhythmiasOther ventricular arrhythmias

Double-Balloon Technique for Retrograde Venous Ethanol Ablation of Ventricular Arrhythmias in the Absence of Suitable Intramural Veins

Da-Wariboko et al. Heart Rhythm, 2020²⁰.

Study Overview

Condition: Ablation-refractory VA

Procedure: Retrograde venous ethanol ablation

Eight patients with LV summit and scar-related VT were referred for ethanol venous ablation after unsuccessful RF ablation. A multipolar catheter (2F octapolar, EPstar Fixed Electrophysiology Catheter, Baylis Medical*; or 7F decapolar DECANAV® catheter, Biosense Webster) was used to collect signals and pace in the CS. A left internal mammary artery (LIMA) or JR4 catheter were used to perform venograms of the target vein. Small vein branches were mapped by configuring an angioplasty wire as a unipolar electrode.

If the target vein had collateral circulation, multiple branches, or optimal signals only in the proximal portion, double-balloon ethanol ablation was performed using the following approach:

- 1. Inflation of two angioplasty balloons in the target branch
- 2. Contrast injection to confirm seal
- 3. 1 cc ethanol injection over a 1-minute period
- 4. Assessment of myocardial staining using contrast injection
- 5. Ethanol injection repeated up to four times for each balloon position
- 6. Deflation of the balloon followed by repositioning and re-injection until PVC was eliminated or VT was non-inducible

- A "double-balloon" strategy can be used to inject ethanol from one balloon while the other balloon occludes large collateral communications to ensure ethanol reaches the targeted myocardium.
- This technique can be useful when RF ablation is unsuccessful, and when the targeted veins are either too large or have multiple branches.

^{*}Baylis Medical Company is a wholly owned subsidiary of Boston Scientific Corporation.

Key publications on idiopathic ventricular arrhythmiasOther ventricular arrhythmias

Radiofrequency Catheter Ablation of Tachycardia in Patients with Congenital Heart Disease

Hebe et al. Pediatric Cardiology, 2000²¹.

Study Overview

Condition: Various tachycardias in patients with congenital heart defects

Procedure: RF ablation

A total of 183 RF ablation procedures in pediatric and adult patients with congenital heart defects were analyzed. Tachycardias were categorized as: Group I) congenital, primary arrhythmogenic substrates (e.g., accessory pathways), or Group II) acquired, secondary arrhythmogenic substrates relating to structural anomalies caused by congenital heart disease or associated surgical intervention (e.g., scars or myocardial fibrosis).

In Group I (congenital), a small 2.5F, 16-pole catheter (Pathfinder® catheter, Cardima) was placed within the CS with the distal electrodes near the lateral aspect of the tricuspid annulus (TA) and proximal electrodes near the posterior portion of the MA. Transseptal puncture was needed for placement of two additional quadripolar catheters in the high right atrium and left ventricle, and two 6F ablation catheters at the midseptal aspect and lateral aspect of the TA. A 2F multielectrode catheter (Corotrax, Sulzer-Osypka GmbH) was used in some patients to map the epicardial aspect of the tricuspid ring through the right coronary artery. Two accessory pathways were located and successfully ablated.

In Group II (acquired), detailed 3-dimensional mapping was used to create an activation map and individualize linear ablation patterns to disrupt the tachycardia propagation in each case.

- With the help of a 2F multielectrode catheter, a reproducible and stable site of local electrogram recording was achievable in patients with healthy coronary arteries; this catheter eventually guided endocardial RF application in the case of unstable electrogram recordings.
- Variations in cardiac anatomy due to congenital heart diseases may lead to misinterpretation of electrophysiological data, encumber diagnosis, and add complexity to the intervention.
- Ablation in the presence of congenital anatomic deviations can accidentally impact other conduction pathways (e.g., cause atrioventricular block).
- Detailed electrophysiologic studies are needed to characterize complex anatomies; new technologies can help individualize ablation strategies and reduce rates of recurrence.

Key publications on idiopathic ventricular arrhythmiasOther ventricular arrhythmias

Idiopathic Basal Crux Ventricular Arrhythmias with Left Bundle Branch Block and Superior Axis – A Comparison with Inferior-Septal Valvular Arrhythmias

Kawamura et al. Journal of Cardiovascular Electrophysiology, 2019²².

Study Overview

Condition: I-VA with left bundle branch block (LBBB) and superior axis

Procedure: RF ablation

The study participants were I-VA patients (n=42) who had a LBBB and superior axis, with no structural heart disease. ECG and clinical characteristics of I-VA with LBBB and superior axis were used to distinguish between VA originating from the basal crux region, TA, or MA. QRS morphology of a 12-lead surface ECG was digitally evaluated. Multielectrode catheters were used to perform an electrophysiology study and mapping. If basal crux-VA was anticipated, a 2F mapping catheter (EPstar fix*, Japan Lifeline) was used to access the narrow MCV. RF ablation (10-50W) was performed using a conventional 4-mm tip catheter to achieve a target impedance drop: 15 Ω for basal crux and 15-20 Ω for TA and MA. Mapping was performed in the inferior-septal left or right ventricle in all patients, as well as proximal CS and proximal MCV in patients with basal crux-VA

- Clinical and ECG characteristics can be used to differentiate basal crux-VA from valvular VA with LBBB and superior axis, and identify the ablation strategy:
 - If basal crux-VA was characterized by superior axis with LBBB, then successful ablation was performed from the proximal CS or proximal MCV.
 - If inferior-septal valvular VA (i.e., TA- and MA-VA) was characterized by superior axis with LBBB, and demonstrated an annulus site from electrogram signals, successful endocardial ablation was performed from the inferior-septal left or right ventricle.

^{*}Note: EPstar Fix (Japan Lifeline) is marketed as EPstar Fixed Electrophysiology Catheter (Baylis Medical) in North America. Baylis Medical Company is a wholly owned subsidiary of Boston Scientific Corporation.

Techniques | Coronary sinus cannulation and mapping

The techniques outlined in this section are as described in published literature^{5, 8, 9, 12-15, 23} with contributions by Dr. Lohit Garg. Additional details can be found in the indicated references. Before use, please refer to individual manufacturer Instructions For Use for product-specific guidance.

- Under sedation, femoral arterial and venous cannulation is performed under ultrasound guidance^{9,15}.
- II. After direct visualization of the CS is achieved using ICE (intracardiac echocardiography), the CS is cannulated and a medium-curl steerable sheath (8.5F SureFlex™ Steerable Guiding Sheath, Baylis Medical* or 8.5F Agilis™ NxT steerable introducer, Abbott) is advanced over a long guidewire⁹. If CS cannulation with the guidewire is challenging, advance the sheath over an ablation catheter or decapolar catheter instead[†].
 - Note: A large-curl steerable sheath can also be used depending on patient anatomy.
- III. If no resistance is experienced, the sheath is advanced via the guidewire to the distal CS and placed above the valve of Vieussens⁹. If navigating the valve of Vieussens is challenging, the CS can be cannulated with a Wholey™ quidewire (Medtronic)[†]. In either case, a quidewire or catheter should always extend beyond the distal tip of the sheath†
- IV. Coronary venography is performed to delineate the coronary venous branches and identify the target vein for mapping (Figure 3)9,16. A non-occlusive venogram in the CS is obtained by injecting contrast[†].

Caution: Do not use a high-pressure injection device for flushing if using the EPstar 6F Diagnostic Catheter with Lumen.

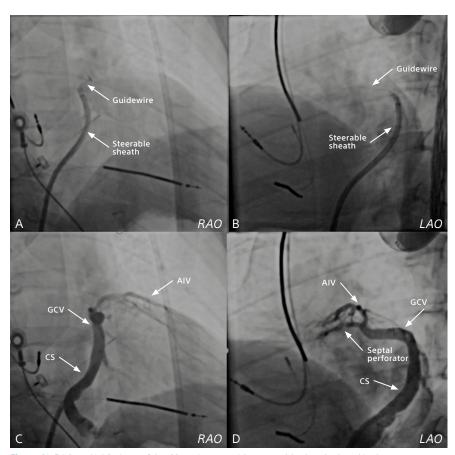


Figure 3*. RAO and LAO views of the CS angiogram with a steerable sheath placed in the coronary sinus above the valve of Vieussens (A, B). Contrast injection highlights the GCV, AIV, septal perforator, and surrounding venous branches (C, D).

^{*}Baylis Medical Company is a wholly owned subsidiary of Boston Scientific Corporation.

[†]Per contributions by Dr. Lohit Garg, electrophysiologist. ‡Images provided courtesy of Dr. Lohit Garg, electrophysiologist.

- V. A 2F octapolar catheter (EPstar Fixed Electrophysiology Catheter, Baylis Medical*), 2.3F 16-pole small mapping wire (Pathfinder® catheter, Cardima)¹², or 4F decapolar mapping catheter (EP Map-iT®, Access Point Technologies) is then advanced and slowly withdrawn to obtain activation mapping in the target area (epicardial true LV summit and basal LV via AIV and GCV, respectively)^{9,16}.
- VI. A guide catheter (e.g., 5F JR catheter or 4F Glidecath® 110 cm, Terumo) is used to selectively cannulate different septal perforator branches. The EPstar 2F catheter is advanced using the guide catheter to perform selective septal perforator activation mapping in the target anatomies, ideally deep in the septal LV (Figure 4)9.

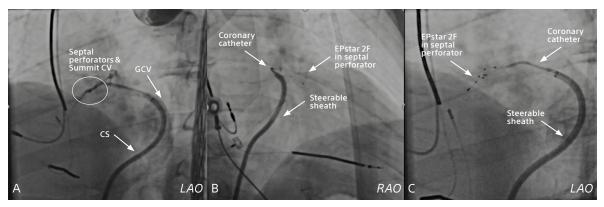


Figure 4*. LAO view of contrast injection highlighting the CS, GCV, septal perforator veins and summit CV (A). The 2F EPstar is advanced through a coronary catheter into the first septal perforator in the LV summit (B, C). LAO is the preferred view for intramural cannulation of the first septal perforator.

VII. Multiple approaches can be used for mapping and targeting different I-VA, as outlined in Table 2.

Note: The 2F EPstar Fixed Electrophysiology Catheter can be integrated with the EnSite™ NavX™ mapping system (Abbott) for activation mapping and creating 3D anatomy⁹. The CARTO® 3 System (Biosense Webster) can also be used for activation mapping, but the 2F EPstar catheter cannot be integrated with the CARTO® output¹⁶.

I-VA to target with ablation	Mapping approach
Septal outflow tract VA	Epicardial true LV summit and intramural activation through first septal perforator ⁹
Epicardial LV tachycardia	Transpericardial AIV-GCV junction, GCV, and distal MCV ¹⁰
LV summit VA	AIV, GCV, or first septal perforator ^{9,14,16,23}

 Table 2. Approaches for mapping and targeting I-VA.

- VIII. Once the catheters are positioned, epicardial (via the AIV/GCV) and intramural (via the septal perforator) activation and propagation mapping is performed^{9,16}.
- IX. Coronary angiography can be performed at this stage to determine whether the selected ablation site is at a safe distance from proximal arterial circulation (> 5 mm) $^{9.16,24}$.
 - Note: Angiography is only required if the ablation site is in the CVS[‡].
- X. An octapolar catheter is used to simultaneously map the first septal perforator and GCV-AIV9.
- XI. The resulting bipolar recordings of the epicardial and endocardial ECG (filtered between 30 and 500 Hz) are analyzed to predict catheter ablation success¹³.

^{*}Baylis Medical Company is a wholly owned subsidiary of Boston Scientific Corporation.

[†]Images provided courtesy of Dr. Lohit Garg, electrophysiologist.

[‡]Per contributions by Dr. Lohit Garg, electrophysiologist.

Techniques | Ablation strategies

After initial mapping and 3D anatomical reconstruction, the ablation target site is determined (Figure 5).

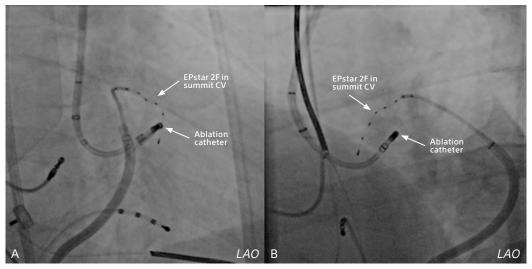


Figure 5*. The EPstar 2F microcatheter advanced into the CS at the LV summit (summit CV, first septal perforator). The ablation catheter was positioned endocardially in close proximity to the earliest activation site intramurally based on fluoroscopy and EAM. RAO (A) and LAO (B) views shown.

There are three patterns of early activation: endocardial, intramural and subepicardial9.

- I. Endocardial RF application can be successfully performed at the earliest endocardial activation site⁹.
- II. Intramural The earliest activation is observed within the distal or mid-poles of the small multipolar mapping catheter and the propagation pattern is from intramural to epicardial to endocardial. Ablation is performed using an endocardial approach that is anatomically opposite to the earliest electrode activation using fluoroscopy, ICE guidance and EAM (electroanatomic mapping). The 2F EPstar catheter is advanced toward the GCV-AIV junction and used to cannulate the septal perforator to record signals⁹.
- III. **Subepicardial** The earliest activation is **within the proximal poles** of the small octapolar mapping catheter and propagation pattern is **epicardial to intramural to endocardial**, representing a subepicardial focus. The ablation catheter is first placed in the endocardium; however, it may be limited by tissue thickness and the distance between the endocardial RF catheter and the epicardial surface⁹. If the VA exit becomes more subepicardial, the mapping catheter is withdrawn and an ablation catheter is used to map the earliest activation site in the AIV/GCV. A coronary angiogram should be performed to determine a safe distance (> 5 mm) from proximal arterial circulation²⁴. RF ablation can be performed at the earliest activation site in the distal AIV/GCV when possible⁹.

^{*}Images provided courtesy of Dr. Lohit Garg, electrophysiologist.

Conclusion

Ablation of idiopathic ventricular arrhythmias can be challenging if mapping is inaccessible from the endocardium, epicardium, or intramural substrate.

Evidence suggests that small diagnostic catheters allow:

- Optimal ablation strategies for idiopathic ventricular arrhythmias 9,12-16,21-23,25.
- Precise identification of the arrhythmia activation site^{9,13,15,16,23}.
- Mapping and identification of earliest site of activation in the LV summit, leading to efficient ablation and potentially lower recurrence rate¹⁻³.

The 2F EPstar Fixed Electrophysiology Catheter (Baylis Medical*) is the smallest commercially available mapping catheter in North America known to facilitate deeper CS mapping for treating idiopathic ventricular arrhythmias^{16,20}.

^{*}Baylis Medical Company is a wholly owned subsidiary of Boston Scientific Corporation.

Glossary of abbreviations

Acronym	Definition
AIV	Anterior interventricular vein
ASOV	Aortic sinus of Valsalva
CS	Coronary sinus
CV	Communicating veins (e.g., summit CV)
CVS	Coronary venous system
EAM	Electroanatomic mapping
ECG	Electrocardiogram
GCV	Great cardiac vein
ICE	Intracardiac echocardiography
I-VA	Idiopathic ventricular arrhythmia
IVS	Interventricular septum
LAO	Left anterior oblique (projection)
LBBB	Left bundle branch block
LIMA	Left internal mammary artery
LVOT	Left ventricular outflow tract
LV	Left ventricle/ventricular (e.g., LV summit, epicardial LV)
LSV	Left sinus of Valsalva
MA	Mitral annulus
MCV	Middle cardiac vein
PVC	Premature ventricular contraction
RAO	Right anterior oblique (projection)
RF	Radiofrequency
RVOT	Right ventricular outflow tract
TA	Tricuspid annulus
VOM	Vein of Marshall
VA	Ventricular arrhythmia
VT	Ventricular tachycardia

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EPstar Fixed Electrophysiology Catheter

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INDICATIONS FOR USE: The EPstar Fixed Electrophysiology Catheter is intended for electrogram recording and pacing during diagnostic electrophysiology studies.

CONTRAINDICATIONS: The EPstar Fixed Electrophysiology Catheter is recommended only for use in cardiac electrophysiological examinations.

WARNINGS: • The EPstar Fixed Electrophysiology Catheter is intended for single patient use only. Do not attempt to sterilize and reuse the catheter. Reuse can cause the patient injury and/or the transmission of infectious disease(s) from one patient to another. Reuse may result in patient complications. • The EPstar Fixed Electrophysiology Catheter must be used with the BMC EPstar Electrophysiology Cable (DEX-10). Attempts to use it with other connector cables can result in electrocution of the patient and/or operator. • Laboratory staff and patients can undergo significant x-ray exposure due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure. • DO NOT use force to push or pull this product in vessels if you feel resistance during insertion of this product [because there is a risk of damaging the blood vessel or heart chamber, and a situation requiring thoracotomy may occur.] • DO NOT use the product in the coronary arteries [it may induce myocardial infarction, arterial perforation, or cardiac tamponade, which may result in death]. • DO NOT use the product in the following patients: • Patients with excessive peripheral vascular diseases that prevent insertion of a sheath in an appropriate size [the vessel may be pierced] • Patients with excessive prolongation of coagulation time contraindicated for antiplatelet therapy and anticoagulation therapy may be required when the product is used] • Patients with a serious allergy to drugs necessary for the procedure such as a contrast medium • Pregnant or possibly pregnant patients • Patients with bacteremia or sepsis • Patients with hypercoagulation or hypocoagulation causing coagulation freacy in the product in the following patients with severe circulation instability or shock • Patients with intracardiac mural thrombus. myocardial and unstable angina.

PRECAUTIONS: • Use only for cardiac electrophysiological examinations and temporary pacing purposes. • Careful catheter manipulation must be performed to avoid cardiac damage, or tamponade. Catheter advancement should be done under fluoroscopic guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the catheter. • Do not bend the EPstar Fixed Electrophysiology Catheter excessively. Excessive bending or kinking of the catheter shaft may damage the integrity of the catheter and may cause patient injury including the detachment or fall of the catheter tip. Care must be taken when handling the catheter. • Pay full attention to the potential for suppression of pacing or malfunction of an ICD due to stimulation by electrophysiology studies of the heart; deal with the matter by changing the settings. • In the case that this product is used in combination with a heart stimulator or external pacemaker, pay careful attention to the location so that the electrodes of this product do not contact other leads. • Store under stable conditions, avoiding vibration and shock (including during transportation).

ADVERSE EVENTS: Adverse events that may occur while using the EPstar Fixed Electrophysiology Catheter include: • Air embolism • Difficulty in catheter retraction • Death • Cardiac tamponade • Sepsis, infections • Vascular tear, perforation or dissection • Arrhythmia with hemodynamic collapse • Ventricular fibrillation/tachycardia • Myocardial infarction/ angina attack • Cerebral infarction/cerebrovascular disorder • Thromboembolism • Hemorrhagic complication • Pneumothorax • Pseudoaneurysm • Pacing failure • Puncture-site complication • Skin disorder by defibrillation • Distal embolization (air, itsue, thrombus) in the lung • Malfunction of implantable pacemaker/ICD • Cardiac valve damage such as valve insufficiency or valvular incompetence • Hypertension/hypotension • Subcutaneous hematom aformation • Ecchymoma formation • Bradycardia including atrioventricular block • Laceration, perforation and dissociation of blood vessel • Difficulty in retracting other concurrently- used medical device from product • Excessive bleeding

EP-1515407-AA

EPstar Fixed Electrophysiology Catheter with Lumen

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INDICATIONS FOR USE: The EPstar Fixed Electrophysiology Catheter with Lumen can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.

CONTRAINDICATIONS: The EPstar Fixed Electrophysiology Catheter with Lumen is recommended only for use in cardiac electrophysiological examinations.

WARNINGS: • The EPstar Fixed Electrophysiology Catheter with Lumen is intended for single patient use only. Do not attempt to sterilize and reuse the catheter. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. Reuse may result in patient complications. • The EPstar Fixed Electrophysiology Catheter with Lumen must be used with the EPstar Electrophysiology Catheter with Lumen must be used with the EPstar Electrophysiology Catheter with Lumen must be used with the EPstar Electrophysiology Catheter with Lumen must be used with the EPstar Electrophysiology Catheter with Lumen must be used with the Catheter Cathe

PRECAUTIONS: • Use only for cardiac electrophysiological examinations. • Careful catheter manipulation must be performed to avoid cardiac damage, or tamponade. Catheter advancement should be done under fluoroscopic guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the catheter. • Do not bend the EPstar Fixed Electrophysiology Catheter with Lumen excessively. Excessive bending or kinking of the catheter shaft may damage the integrity of the catheter and may cause patient injury including the detachment or fall of the catheter tip. Care must be taken when handling the catheter. • In the case that this product is used in combination with a heart stimulator or external pacemaker, pay careful attention to the location so that the electrodes of this product do not contact other leads.

ADVERSE EVENTS: Adverse events that may occur while using the EPstar Fixed Electrophysiology Catheter with Lumen includes: • Air embolism • Difficulty in catheter retraction • Death • Ventricular fibrillation/ tachycardia • Sepsis, infections • Arrhythmia with hemodynamic collapse • Cardiac tamponade • Myocardial infarction/ angina attack • Pseudoaneurysm • Access-site complication • Hemorrhagic complication • Bradycardia including atrioventricular block • Thromboembolism • Distal embolization (air, tissue, thrombus) in the lung • Pneumothorax • Subcutaneous hematoma formation • Malfunction of implantable pacemaker/ ICD • Cerebral infarction/cerebrovascular disorder • Laceration, perforation and dissociation of blood vessel • Cardiac valve damage such as valve insufficiency or valvular incompetence • Hypertension/ hypotension • Cell damage

EP-1514904-AA



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