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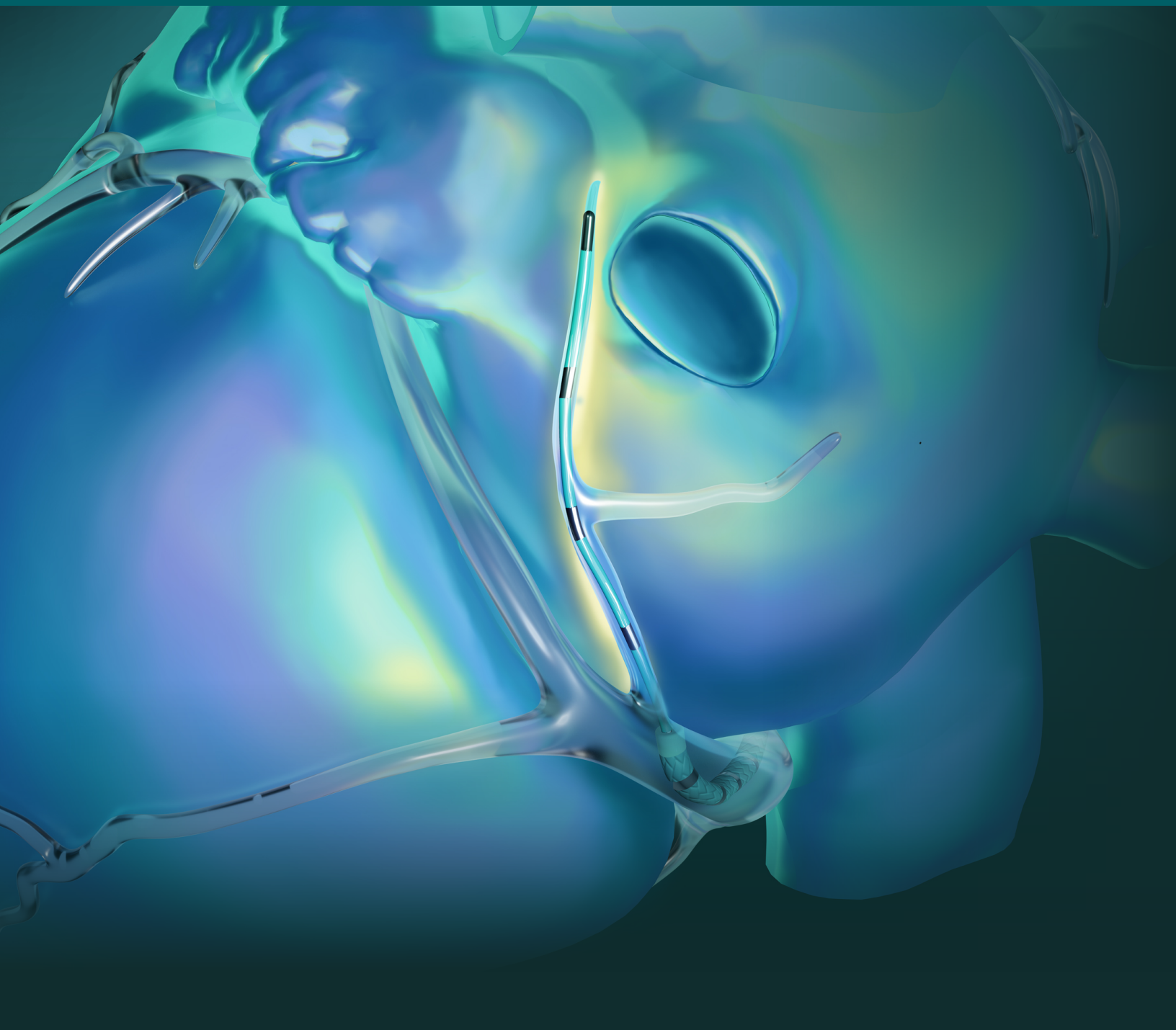
Vein of Marshall Pacing and Mapping

Published Literature and Techniques



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Background | Anatomy

The ligament of Marshall (LOM) is an epicardial vestigial fold that contains **the oblique vein of Marshall (VOM),** the myocardial sleeve (which includes the Marshall bundle, MB) and autonomic nerves[1]. The LOM is located in the epicardial aspect of the left lateral ridge (LLR), a structure found between the left atrial appendage (LAA) and the left pulmonary veins (PVs). This location makes the LLR an important yet challenging site for completing endocardial catheter ablation lines in the treatment of **atrial fibrillation (AF)[2].** The Marshall bundle (MB) gradually changes into multiple muscle fibers, which insert into the anterior epicardium of the left atrium (LA) and the left PVs (Figure 1). The VOM is located in the epicardial aspect of the mitral isthmus and usually connects to the coronary sinus (CS) proximal to the valve of Vieussens with a posterior course along the LLR[2,3].

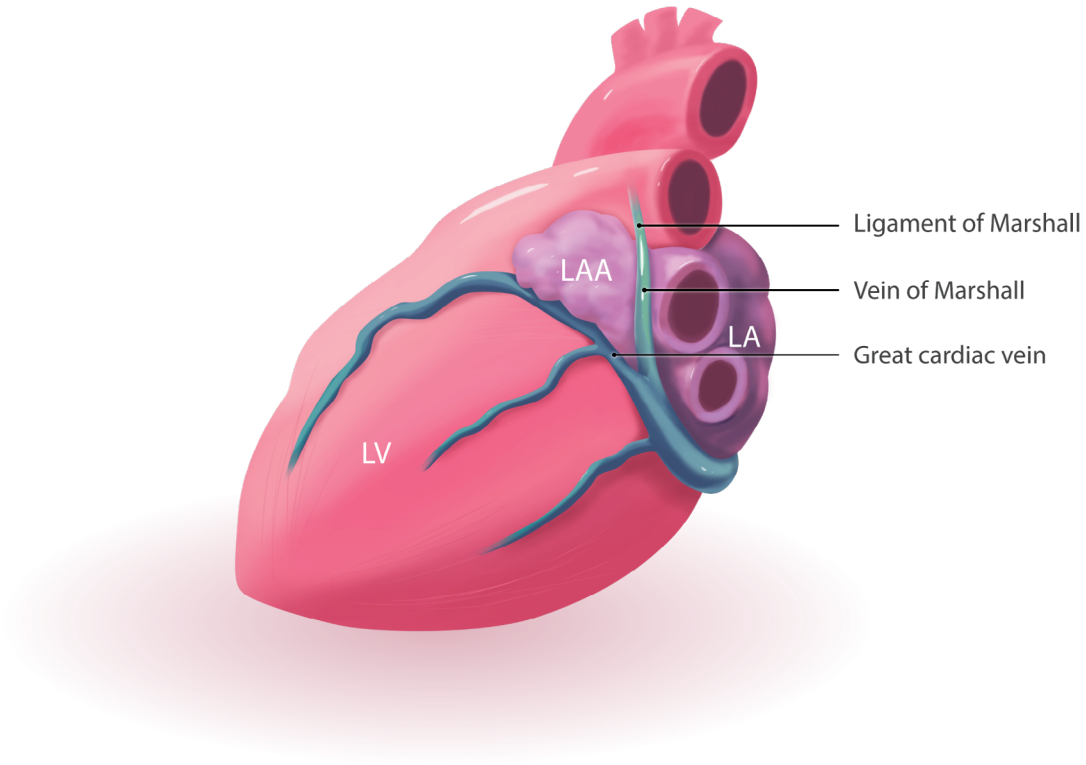

Figure 1. Illustration of the heart indicating proximity of the ligament of Marshall (LOM), Marshall bundle (MB), and vein of Marshall (VOM) to the left atrium (LA), left atrial appendage (LAA), and left pulmonary veins (PV).

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Background | Relevance of VOM

The VOM and associated tissue of the LOM are implicated in the pathogenesis of AF through multiple mechanisms[4,5].

- **Source of ectopic beats that trigger AF.**
- **Conduction path to surrounding myocardial tissue and left PVs.**
- **Conduit for autonomic innervation of the left atrium that can contribute to AF maintenance.**

The VOM is located within the mitral isthmus, a critical ablation site for treating perimitral atrial tachycardia (AT)[2,5]. Incomplete ablation of the mitral isthmus is proarrhythmogenic and can increase the risk of recurrent flutter by up to 4 times[2]. The fibers connecting the VOM to the PVs may bypass endocardial ablation lesions, which can lead to PV reconnection[4]. For example, recordings of double potentials from the left superior PV may come from the LOM[6]. These potentials can be ablated from both the endocardium with radiofrequency (RF) ablation and from the epicardium with VOM ethanol injection[7].

In addition, the VENUS-AF trial (Vein of Marshall Ethanol iNfusion in Untreated perSistent Atrial Fibrillation) demonstrated that VOM ethanol infusion in de novo catheter ablation in patients with persistent AF improved the likelihood of freedom from AF or AT at 6 and 12 months[5].

The location, size, tortuosity, and anatomic variability of the LOM and VOM require specialized tools and techniques to map and effectively ablate innervations implicated in the pathogenesis of AF and perimitral atrial flutter[2,8].

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Key Publications | VOM Ethanol Infusion and RF Ablation

Catheter Ablation of the VOM from the Endocardium

Kashimura et al. *Heart Rhythm Case Reports*, 2017[7].

Study Overview

Condition: Persistent AF, Symptomatic AT

Procedure: Catheter ablation from the endocardium to visualize the electrically isolated area of the VOM

A 64 year old male had recurrent AF 9 months after initial RF ablation of a complex fractionated atrial electrogram area failed to terminate the AF or convert it to AT. Mapping and pacing of the VOM was attempted using a 2F octopolar catheter (EPstar Fixed Electrophysiology Catheter, Japan Lifeline). The VOM was ablated from the endocardium, specifically targeting the 2F catheter in the VOM using fluoroscopy. Ethanol infusion of the VOM was performed when ectopic activity was recorded from the proximal VOM after ablation.

Highlights

- Electrode catheter insertion in the VOM could serve as an anatomic indicator for the RF ablation target site, and could indicate when the VOM is electrically isolated.
- Echocardiac contrast injection in the VOM showed earliest contrast appearance in the LA adjacent to the left PVs.
- The most distal VOM region was the focus of ectopic activity, and the most proximal region was connected to the CS musculature.
- Ethanol infusion in the VOM produced a low-voltage area on the posterior wall of the LA, and the anterior aspect of the left PVs.
- Ablation of the middle and distal aspect of the VOM interrupted electrical connections, electrically isolating the distal half of the VOM.

Key Publications | RF Ablation

RF Ablation of Left Lateral Ridge to Isolate MB

Han et al. *Heart Rhythm*, 2010[1].

Study Overview

Condition: Persistent AF

Procedure: Marshall bundle mapping and RF ablation

VOM endocardial mapping using a 1.5F quadripolar catheter (Pathfinder, Cardima) was possible in 45% of the 72 patients in the study. In patients where the VOM could not be cannulated, epicardial mapping of the MB was conducted via the subxiphoid pericardial puncture. Additional mapping followed using a deflectable duodecapolar catheter and an 8F SL transseptal sheath (St. Jude Medical) to stabilize the MB recordings. To isolate the MB, RF energy was applied on the left lateral ridge. However, most patients required additional ablation of the left lateral isthmus, the CS, or epicardial sites. Dissociation of the MB or exit block by selective MB pacing was used to confirm successful isolation.

Highlights

- The 1.5F quadripolar catheter may be maneuvered within the VOM to determine MB connection type.
- The MB bypasses the tract between the CS, and the left PVs when more than one connection is present, and can serve as a trigger for paroxysmal AF.
  - Single connection: The MB may initiate AF through ectopic activity, but may not contribute majorly to AF maintenance.
  - Double connection: The MB – PV connection offers a channel between the PVs and the LA through the CS muscle sleeves. Failure to eliminate this accessory pathway results in electrical stimulation within the PVs followed by LA activation, which might be interpreted as failed PV isolation.
  - Multiple connections: The MB has the highest dominant frequency during sustained AF where the complex electrical connection pattern between the MB and the LA provides a substrate for reentry. In this case, the MB is not always activated passively through neighboring AF wavefronts, but is capable of independent rapid activation.

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Key Publications | RF Ablation

RF Ablation at the Insertion Site of the VOM

Hwang et al. *Circulation*, 2000[6].

Study Overview

Condition: Paroxysmal AF

Procedure: RF ablation aimed at the insertion site of the VOM

A 1.5F quadripolar catheter (Pathfinder, Cardima) was inserted into the VOM to record and pace in 28 patients with recurrent AF. Electrograms were attained during sinus rhythm and spontaneous or induced atrial tachyarrhythmias.

Highlights

- Triggers of focal AF episodes resided in the MB, but not the PVs.
- RF ablation guided by the diagnostic catheter in the VOM successfully terminated atrial tachyarrhythmias and prevented reinduction; no additional RF applications were needed in the PVs.
- Using the diagnostic catheter in the VOM as a guide for RF ablation allowed lesion placement in the posterolateral LA between the MB insertion and the ostium of the left inferior PV, which resulted in successful treatment of focal AF.

Key Publications | RF Ablation

RF Ablation on Opposite Side of the VOM

Kawamura et al. *Heart Rhythm*, 2018[9]

Study Overview

Condition: AT

Procedure: RF ablation

The patient was a 76 year old male with a history of AF in which a leap-frog pattern was identified through endocardial mapping in the LA. The activation signal bypassed the ablation scars to reach its destination along the intended clockwise perimetral AT. A 2F octopolar catheter (EPstar Fixed Electrophysiology Catheter, Japan Lifeline) was advanced into the VOM for mapping and pacing. An RF ablation catheter was placed on the opposite side of the VOM. AT was terminated with RF ablation, and bidirectional block was observed with differential pacing on either side of the mitral isthmus.

Highlights

- Ablation of AT is possible through RF ablation on the opposite side of the VOM.

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Key Publications | RF Ablation

Ridge Ablation

Wakabayashi et al. *Circulation: Arrhythmia and Electrophysiology*, 2016[10].

Study Overview

Condition: Persistent AF

Procedure: LLR ablation

A 66 year old male underwent circumferential pulmonary vein isolation (PVI) of all four PVs, linear ablation of the LA roof and mitral isthmus, and confirmation of complete conduction block of the LA roofline. An epicardial conduction pathway through the MB was suspected to bypass the endocardial mitral isthmus line. A 2F octopolar catheter (EPstar Fixed Electrophysiology Catheter, Japan Lifeline) was inserted into the VOM for mapping and pacing. The activation sequence of the VOM was distal to proximal during LAA pacing. As such, electric conduction from the LAA to the VOM via the distal MB to LA connection was suspected. RF energy was applied at the LLR, defined as the ridge between the left PVs and the LAA . Following ridge ablation, the VOM activation sequence during LAA pacing changed from proximal to distal, indicating successful MB to LA disconnection.

Highlights

- Ridge ablation allowed for complete mitral isthmus block by disconnecting the MB from the LA.
- The MB has an important role in the conduction pathway for perimitral AT.
- VOM mapping and pacing with a 2F octopolar electrode catheter can identify epicardial conduction pathways via the MB that bypass the endocardial mitral isthmus line.
- Ridge ablation is useful in cases where challenging VOM anatomy (e.g., absent, tortuous, or small) complicates ablation catheter insertion.
- Ridge ablation does not involve complex procedural steps, such as additional catheter cannulation into the VOM, and is believed to be the best option for initial attempts to create the MB conduction block.
- Blocking MB conduction by ridge ablation can be complicated by multiple MB – LA connections; alternative procedures may be preferable in such cases.

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Key Publications | VOM Ethanol Infusion

Mitral Isthmus Block

Baez-Escudero et al. *Heart Rhythm*, 2012[2].

Study Overview

Condition: Microreentrant tachycardia involving mitral annulus – perimitral flutter

Procedure: Bidirectional mitral isthmus block using VOM ethanol infusion

VOM cannulation, mapping, and pacing was achieved using a 1.7F quadripolar catheter (Pathfinder, Cardima) in 50 of 71 study patients. Spontaneous flutter was mapped and entrained from the proximal CS, distal CS, and the VOM. Perimitral flutter was diagnosed when a reentrant circuit was mapped around the mitral annulus and entrained from the proximal and distal CS, leading to a post-pacing interval of 30 ms of the cycle length. VOM ethanol infusion was used for ablation to achieve mitral isthmus block.

Highlights

- The VOM and its neighboring tissue are within the perimitral flutter circuit.
- VOM ethanol infusion allowed for 100% bidirectional mitral isthmus block when VOM cannulation was feasible; RF ablation time was minimal regardless of whether patients had prior ablations.
- VOM ethanol infusion alone can acutely terminate perimetral flutter in a fraction of patients (5/19 patients) with previous mitral isthmus ablation.

Key Publications | VOM Ethanol Infusion

Disconnection of Reconnected Left PVs

Dave et al. .*Journal of Cardiovascular Electrophysiology*, 2012[4].

Study Overview

Condition: AF or atrial flutter

Procedure: VOM ethanol infusion

Successful VOM cannulation was performed in 54 of 61 study patients. Of those 54 patients, 32 underwent VOM ethanol infusion. A 1.7F quadripolar catheter (Pathfinder, Cardima) was inserted into the VOM to record and pace. To assess the role of the VOM in providing a pathway for reconnection, pacing was performed from the VOM and the reconnected PVs. The advancement of the PV potential relative to the atrial far-field signal during VOM pacing indicated a VOM-mediated connection. Ablation was performed using VOM ethanol infusion, which disconnected the reconnected left inferior PV, and disconnected the left superior PV.

Highlights

- Left PV reconnection after PVI can occur through epicardial connections via the VOM in a minority of cases.
- VOM ethanol infusion eliminated VOM electrical activity and disconnected the left PVs regardless of the connection mechanism, eliminating left pulmonary arrhythmogenesis.
- VOM ethanol infusion eliminated complex potentials that have been linked to the genesis and maintenance of AF.
- Chemical ablation through the VOM can assist in achieving lesion transmurality, regardless of the patterns of the VOM-PV connections.

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Findings from the VENUS-AF (Vein of Marshall Ethanol iNfusion for Untreated perSistent AF) **Trial**

Valderrábano et al. *JAMA*, 2020[5].

Study Overview

Condition: Persistent AF

Procedure: First time catheter ablation alone vs. VOM ethanol infusion in addition to catheter ablation

343 patients from 12 referral centers were randomized 1:1.15 into two groups comparing rhythm control effectiveness in de novo ablation of AF. The first group underwent catheter ablation alone (158 patients), and the second group underwent VOM ethanol infusion prior to catheter ablation (185 patients). Clinical assessment of 12-lead electrograms were obtained at baseline and at 1, 3, 6, 9 and 12 months after initial ablation. Patients underwent continuous 1-month electrocardiographic monitoring at 6 and 12 months after ablation.

Highlights

- Technical failure to canulate the VOM occurred in 30 patients.
- VOM ethanol infusion led to low-voltage area in 13/155 patients and left inferior PV isolation in 33/155 patients.
- There were no complications attributed to VOM ethanol infusion.
- The overall procedure, fluoroscopy, and LA instrumentation time were shorter in the catheter ablation group with longer total RF application time.
- The addition of VOM ethanol infusion to catheter ablation increased the likelihood of freedom from AF and AT at 6 and 12 months.
  - Compared to catheter ablation alone, treatment with VOM ethanol infusion combined with catheter ablation resulted in:
    - 10.4% lower AF burden ($p = 0.01$).
    - 11.2% greater freedom from AF or AT or repeat procedures without use of antiarrhythmic drugs ($p = 0.04$).
    - 11.4% higher freedom from AF after multiple procedures ($p = 0.04$).
    - 29.3% greater success in achieving perimitral block ($p < 0.001$).

Techniques | VOM Cannulation

The techniques described in this section are based on published studies[2,3,4,5,7,8,9] as well as a contemporary review paper on VOM ethanol infusion in the treatment of atrial fibrillation[11].

Consult the 2F EPstar Fixed Electrophysiology Catheter Instructions For Use for appropriate use of the device.

I. Under general anesthesia, a quadripolar catheter is positioned at the His bundle and a decapolar catheter is introduced into the CS via the right internal jugular vein, the left subclavian vein, or femoral vein under fluoroscopy using a CS sheath or an 8F sheath (fixed or steerable)[3,8,11].

II. A 5F or 6F left internal mammary artery (LIMA) guiding catheter with a Y-connector for contrast injection and for angioplasty wire (e.g. 0.014-inch BMW) placement, is inserted in the CS through the 8F fixed or steerable sheath[2,3,8,11].

III. The LIMA catheter tip is positioned posteriorly towards the assumed VOM for contrast injection, and then moved gently up and down[2,3,11].

Note: If the VOM cannot be visualized after several contrast injections, the LIMA catheter can be exchanged for a pulmonary artery catheter to perform angiography with proximal balloon occlusion[3].

IV. A balloon occlusion venogram using a balloon catheter (2x8 mm) is performed to delineate CS anatomy[2,8].

V. Presence of the VOM is confirmed when a posteriorly directed vein branch is visible in the anterior oblique projection (Figure 2)[8].

VI. The sheath is advanced to cannulate the VOM[2].

VII. Angiographic contrast is injected to confirm access to the VOM[2].

VIII. A small 1.7F quadripolar catheter (Pathfinder; Cardima) or 2F octopolar catheter (EPstar Fixed Electrophysiology Catheter; Baylis Medical) is inserted in the VOM (Figure 3)[2,4,5,7,9].

IX. Marshall bundle mapping can be done for patients where the VOM cannot be cannulated[1].

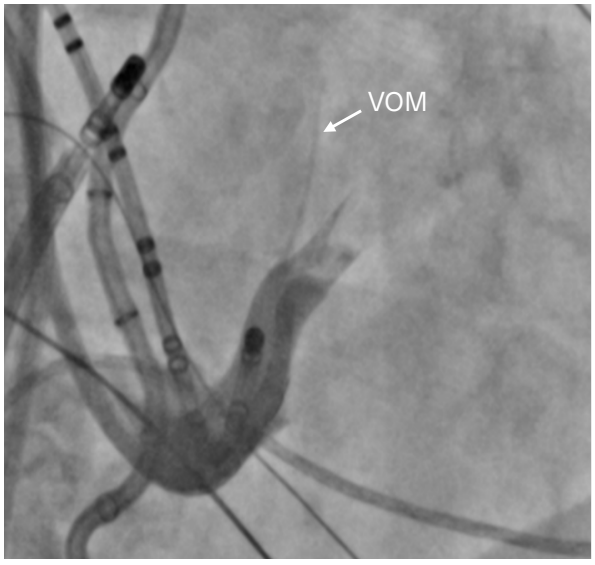

Figure 2*. Initial coronary sinus venogram showing the VOM (white arrow).

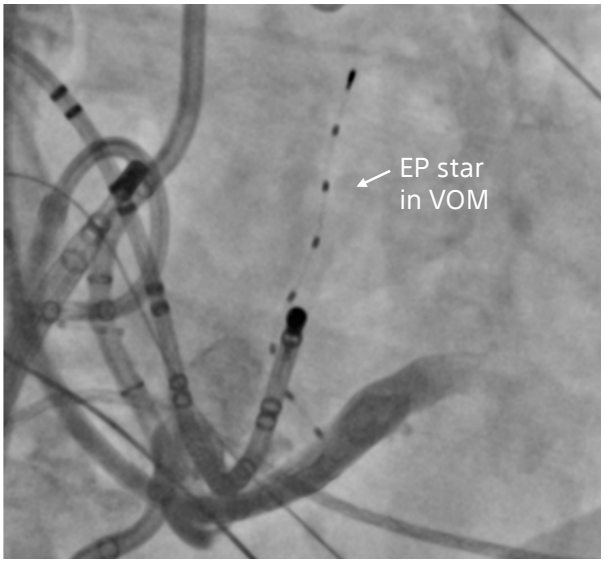

Figure 3*. Venogram showing VOM cannulation using EPstar 2F Fixed Electrophysiology Catheter (white arrow).

* Images provided courtesy of Dr. Akanibo Da-wariboko, Houston Methodist DeBakey Heart & Vascular Center

Techniques | Ethanol Infusion

The techniques described in this section are based on published literature.[2,3,4,5,7,8,9]
Consult the 2F EPstar Fixed Electrophysiology Catheter Instructions For Use for appropriate use of the device.

I. After mapping, the small 1.7 F quadripolar catheter (Pathfinder, Cardima), or EPstar 2F Fixed Electrophysiology Catheter (Baylis Medical) is removed.

II. A percutaneous transluminal coronary angioplasty guidewire with a preloaded coronary dilatation balloon catheter (e.g. Voyager OTW) is introduced via the Y connector through the LIMA catheter[2,3].

Note: The size of the coronary dilatation balloon is estimated relative to the 6F 5F LIMA catheter (usually 1.5-2.5 mm in diameter and 6-8 mm in length)[3,11].

III. The angioplasty guidewire is gently introduced into the VOM with rotational movement, far enough to provide adequate support for subsequent advancement of the balloon over the wire[3].

IV. An angioplasty balloon catheter is advanced over the wire as distally as possible, and inflated to 2-4 atm until a small resistance is felt before wire removal (Figure 4)[2,3].

V. The VOM is visualized by direct contrast injection into the balloon catheter to check for leakage or collateral blood flow back to the CS[3].

VI. Depending on the length of the VOM, up to 4 balloon occlusive injections of 98%-100% ethanol (1 cc over 2 mins) are delivered, starting at the most distal location in the VOM[2,4].

VII. The balloon is slowly retracted 1 cm after each injection, so that the last injection is given from the most proximal portion of the VOM (at the VOM ostium)[2,11].

VIII. The diagnostic catheter is reinserted into the VOM (Figure 5) to record signals and verify ablation (Figure 6)[4].

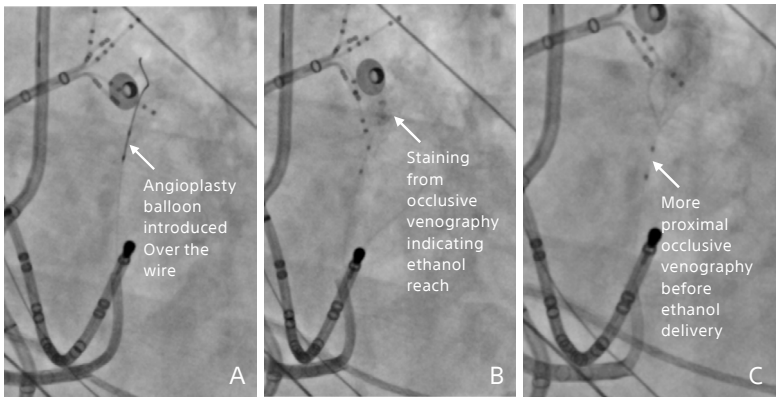

Figure 4*. (A) Angioplasty balloon in the VOM (white arrow). (B) Staining from occlusive venogram, suggesting the extent of ethanol reach (white arrow). (C) Proximal occlusive venogram (white arrow) prior to ethanol delivery.

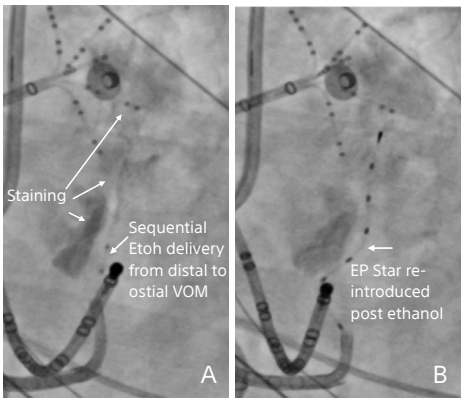

Figure 5*. Venogram showing (A) sequential ethanol delivery from the distal to ostial VOM (white arrows), and (B) reintroduction of EPstar 2F Fixed Electrophysiology Catheter into the VOM post-ethanol infusion.

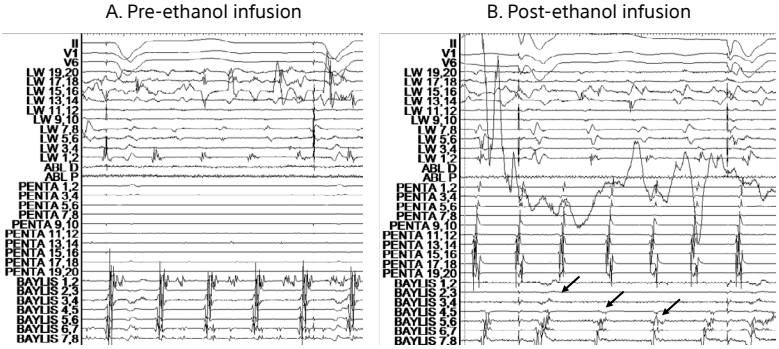

Figure 6*. Intracardiac electrograms (A) before and (B) after VOM ethanol infusion showing VOM signal attenuation (black arrows) measured by the distal electrodes of EPstar 2F Fixed Electrophysiology Catheter.

* Images provided courtesy of Dr. Akanibo Da-wariboko, Houston Methodist DeBakey Heart & Vascular Center

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Conclusion

Published clinical evidence shows that small diagnostic catheters, such as the 2F EPstar Fixed Electrophysiology Catheter, allow for:

- Mapping and pacing of small distal CS branches, including the VOM[1,2,4,6,7,9,10,12].
- Identification of the precise site of arrhythmia[1,2,4,6,7,9,10,12].

The feasibility of mapping and pacing the VOM using a small diagnostic catheter can lead to less RF ablation and potentially reduce the need for repeat procedures[2,6].

The 2F EPstar Fixed Electrophysiology Catheter offered by Baylis Medical is the only commercially-available multipolar 2F microcatheter in North America that allows for electrogram recording and pacing during diagnostic electrophysiology studies.

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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 [the 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 disorder • Patients not eligible for thoracotomy procedures • Patients with tricuspid replacement if the product needs to pass a cardiac valve • 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, tissue, thrombus) in the lung • Malfunction of implantable pacemaker/ICD • Cardiac valve damage such as valve insufficiency or valvular incompetence • Hypertension/hypotension • Subcutaneous hematoma formation • 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

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 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 Cable (DEX-10/DEX-14). 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 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 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 [the 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 disorder • Patients not eligible for thoracotomy procedures • Patients with tricuspid replacement if the product needs to pass a cardiac valve • Patients with severe circulation instability or shock • Patients with intracardiac mural thrombus, myocardial and unstable angina

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

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