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Da-Wariboko et al, Heart Rhythm, Volume 17, Issue 5, (Supplement, S169-S170), May 2020

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Miniaturized Octopolar Catheter For Mapping In Cardiac Veins: Early Experience Guiding Ethanol Infusion In The Vein Of Marshall And LV Summit Veins

INTRODUCTION

- Cardiac vein mapping enables characterization of ventricular arrhythmogenic substrates arising deep in the septum for left ventricular (LV) summit ventricular arrythmias or epicardially from the vein of Marshall (VOM).
- Small vein mapping also enables verification of ablation during venous ethanol infusion.
- Previously, small multipolar catheters were not available for small vein mapping. This study tests the utility of the 2F catheter for small vein mapping in the VOM and septal veins in the LV summit.
- Coronary venous angiogram-guided mapping was performed in 12 consecutive cases using the octopolar **EPstar** 2F Fixed Electrophysiology Catheter (Baylis Medical*).

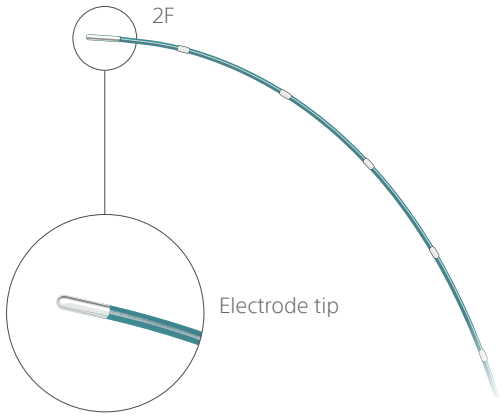

Figure 1. EPstar 2F Catheter with flexible shaft and atraumatic electrode at the distal tip.

RESULTS

- Vein of Marshall:
  - The **EPstar** 2F Catheter was used to assess endo-epicardial activation in mitral isthmus via VOM (n=7)
  - Successful cannulation of VOM revealed endo-epicardial dissociation with opposite propagation direction
- Septal veins:
  - The **EPstar** 2F Catheter was used to successfully cannulate and map ventricular arrhythmias arising from the LV summit (n=4)
  - Mapping identified target veins for ethanol infused ablation
- Epicardial veins:
  - Mapping using the **EPstar** 2F Catheter identified ventricular tachycardia substrates (n=1)
- Cannulation of small veins post-ethanol infusion allowed for confirmation of eliminated local electrograms.

DISCUSSION AND CONCLUSIONS

- The **EPstar** 2F Catheter enabled successful mapping and pacing through small veins (e.g. VOM, LV summit, and epicardial veins) to:
  - Detect activation patterns
  - Characterize epicardial signals
  - Verify ethanol induced ablation

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Brief Summary | **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

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