



Highlights from:

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Radiofrequency-Assisted Transseptal Access for Atrial Fibrillation Ablation Via a Superior Approach

INTRODUCTION

- ▶ This study reports outcomes of transseptal puncture and atrial fibrillation ablation from a superior approach in patients without access to the inferior vena cava (IVC) using dedicated radiofrequency (RF) tools.

METHODS

- ▶ Retrospective analysis was performed on 15 patients undergoing RF ablation using the superior approach after an initial failed attempt using the femoral route.

Transseptal puncture

- ▶ Ultrasound-guided superior access was obtained using the internal jugular, subclavian, or axillary veins; radial arterial access was used for continuous blood pressure monitoring.
- ▶ **SupraCross™** Steerable Sheath (Baylis Medical*) or **Agilis™** EPI Steerable Introducer (Abbott) were advanced into the right atrium and deflected towards the interatrial septum.
- ▶ A dedicated RF needle or wire (Baylis Medical) were used for transseptal puncture under intracardiac echocardiography (ICE) and fluoroscopy guidance.
- ▶ The steerable sheath was advanced into the left atrium over the pigtail **SupraCross™** RF Wire or **ProTrack™** Pigtail Wire (Baylis Medical).

Radiofrequency ablation

- ▶ Electroanatomic mapping (CARTO® 3 System, Biosense Webster) and wide antral pulmonary vein isolation using a THERMACOOL® catheter (Biosense Webster) were performed.

RESULTS

- ▶ Single (8 patients) or double (7 patients) transseptal access was obtained within 16.1 ± 4.8 min.
- ▶ Mapping and ablation were performed successfully in 100% of cases within 227.9 ± 120.7 min.

DISCUSSION AND CONCLUSIONS

- ▶ Superior transseptal access for AF ablation in patients with interrupted IVC can be achieved safely and effectively from a superior approach using dedicated RF transseptal devices.
 - May also provide a simpler strategy for delivery of endocardial left ventricular leads

- ▶ Downward force on a standard transseptal needle and non-deflectable sheath from a superior approach can dislodge the contact site on the fossa ovalis.
- ▶ Use of a steerable sheath and stiff pigtail RF wire supported left atrial catheterization without difficulty.
- ▶ To better engage the fossa in two patients, the **Agilis™** EPI sheath was exchanged for the **SupraCross™** sheath.
 - **SupraCross™** sheath had a smoother sheath-dilator transition than the **Agilis™** sheath
 - **SupraCross™** sheath had a more flexible distal end that can be easily bent with the dilator in place for a tighter angle of deflection than the **Agilis™** sheath (Figure 1)
- ▶ Technical considerations for performing AF ablation from the superior approach:
 - ICE images are inverted compared to standard view; descending aorta can be used as a reference
 - Superior-anterior transseptal puncture improves catheter contact and stability in the left atrium
 - Left axillary vein access may improve operator ergonomics over right internal jugular vein

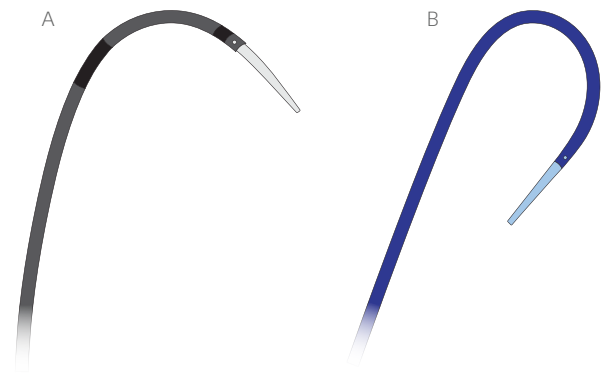


Figure 1. Graphical reconstruction of sheath curvature presented in Liang et al using the (A) **Agilis™** EPI sheath or (B) **SupraCross™** sheath with flexible dilator.

Brief Summary | **SupraCross™** Steerable Sheath

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 SupraCross™ Steerable Sheath kit is indicated for introducing various cardiovascular catheters to the heart, including the left side of the heart through the interatrial septum.

CONTRAINDICATIONS: There are no known contraindications for this device.

WARNINGS: • Laboratory staff and patients can undergo significant x-ray exposure during interventional procedures 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. • The SupraCross™ Steerable Sheath kit is intended for single patient use only. Do not attempt to sterilize and reuse the SupraCross™ Steerable Guiding Sheath kit. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another. • Care should be taken to ensure that all air is removed from the sheath before infusing through the side port. • Do not attempt direct percutaneous insertion of the sheath without the dilator as this may cause vessel injury. • DO NOT attempt to insert or retract the guidewire through a metal cannula or a percutaneous needle, which may damage the guidewire and may cause patient injury.

PRECAUTIONS: • Careful manipulation must be performed to avoid cardiac damage, or tamponade. Sheath, dilator and guidewire advancement should be done under fluoroscopic guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device. • Avoid deflecting distal end of sheath during delivery and removal, otherwise damage to vessels may occur. • The SupraCross™ Steerable Sheath kit is not compatible with transseptal needles such as the "NRG™ Transseptal Needle". • Do not reshape the distal tip or curve of the guidewire. Excessive bending or kinking of the distal curve may damage the integrity of the wire or coating and lead to patient injury.

ADVERSE EVENTS: Adverse events that may occur while using the SupraCross™ Steerable Sheath include: • Infection • Air embolus • Local nerve damage • Vasovagal reaction • Dissection • Vessel spasm • AV fistula formation • Atrial septal defect • Pseudoaneurysm • Aortic puncture • Arrhythmias • Perforation and/or tamponade • Hematoma • Hemorrhage • Catheter entrapment • Embolic events • Stroke • Valve damage • Myocardial infarction • Pacemaker/defibrillator lead displacement • Pulmonary edema • Coronary artery spasm and/or damage • Vessel trauma • Pericardial/pleural effusion

EP-1515304-AA

Brief Summary | **SupraCross™** RF Wire

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 SupraCross™ RF Wire is indicated for creation of an atrial septal defect in the heart.

CONTRAINDICATIONS: The SupraCross™ RF Wire is not recommended for use with any conditions that do not require the creation of an atrial septal defect. The Connector Cable is not recommended for use with any other RF Generator or any other device.

WARNINGS: • Laboratory staff and patients can undergo significant x-ray exposure during RF puncture procedures 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. • The SupraCross™ RF Wire and Connector Cable are intended for single patient use only. Do not attempt to sterilize and reuse either devices. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another. Reuse may result in patient complications. • The SupraCross™ RF Wire must be used with the Connector Cable provided. Attempts to use it with other connector cables can result in electrocution of the patient and/or operator. • Do not use the SupraCross™ RF Wire with electrocautery or electrosurgery generators, connector cables or accessories as attempted use can result in patient and/or operator injury. • The Connector Cable must only be used with the RFP-100A Baylis RF Generator and the included SupraCross™ RF Wire. Attempts to use it with other RF Generators and devices can result in electrocution of the patient and/or operator. • The SupraCross™ RF Wire must be used with 0.035" compatible transseptal sheath and/or dilator devices. Use of incompatible accessory devices may damage the integrity of the SupraCross™ RF Wire or accessory devices and may cause patient injury. • The SupraCross™ RF Wire has only been validated for transseptal puncture use through SupraCross™ dilators which have been demonstrated to provide the required support for optimal function. • The SupraCross™ RF Wire is not intended for use with neonatal patients (i.e. less than one month of age). Do not attempt to treat neonatal patients with the SupraCross™ RF Wire.

PRECAUTIONS: • In order to prevent the risk of ignition, ensure that flammable materials are not present in the room during RF power application. • Do not bend the SupraCross™ RF Wire or the Connector Cable. Excessive bending or kinking of the wire shaft, distal curve of the wire and/ or the Connector Cable may damage the integrity of the device components and may cause patient injury. Care must be taken when handling the SupraCross™ RF Wire and Connector Cable. • Careful manipulation of the SupraCross™ RF Wire must be performed to avoid vessel trauma. If resistance is encountered, DO NOT use excessive force to advance or withdraw the SupraCross™ RF Wire or ancillary sheath and/or dilator assembly. Excessive force may lead to bending or kinking of the device limiting advancement and retraction of sheath and/or dilator device. • Avoid RF energy delivery of the SupraCross™ RF Wire with incompatible dilator or cannula devices, which may lead to patient burns, ineffective puncture or failure to puncture. • The Baylis RF Generator is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the SupraCross™ RF Wire and/or DIP electrode, particularly when operating the device. • During power delivery, the patient should not be allowed to come in contact with ground metal surfaces.

ADVERSE EVENTS: Adverse events that may occur while creating an atrial septal defect include: • Tamponade • Sepsis/Infection • Thromboembolic episodes • Vessel perforation • Atrial Fibrillation • Myocardial Infarction • Vessel spasm • Sustained arrhythmias • Atrial Flutter • Hemorrhage • Vascular thrombosis • Perforation of the myocardium • Hematoma • Allergic reaction to contrast medium • Ventricular Tachycardia • Pain and Tenderness • Arteriovenous fistula • Pericardial effusion • Tachycardia • Vascular Trauma • Additional Surgical Procedure • Wire entrapment/entanglement • Foreign body/wire fracture

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Brief Summary | **ProTrack™** Pigtail Wire

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 ProTrack™ Pigtail Wires are intended for use in percutaneous transseptal procedures to introduce and position catheters and other interventional devices within the left heart. The device is not intended for use in the coronary arteries.

CONTRAINDICATIONS: There are no known contraindications for this device.

WARNINGS: • DO NOT push, auger, withdraw or torque a pigtail wire against resistance until the cause of the resistance has been determined. Applying excessive force against unexpected resistance may cause damage to the pigtail wire, interventional device and/or vessel/organ. • When the pigtail wire is exposed to the vascular system, it should be manipulated while under high-resolution imaging guidance including fluoroscopy and/or echocardiography. Improper visualization of the guidewire may lead to misplacement, dissection, or perforation. • Inspect the pigtail wire prior to use for coil separation, kinking, appropriate distal tip flexibility or breakage. If the pigtail wire is damaged or defective, do not use it. Using a damaged or defective pigtail wire may cause vasculature damage and/or compromise pigtail wire performance. • Laboratory staff and patients can undergo significant X-ray exposure during interventional procedures due to the continuous usage of fluoroscopic imaging. The 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.

ADVERSE EVENTS: Potential complications associated with the use of the pigtail wire include, but are not limited to: • Vessel Perforation/Dissection/Trauma or Damage • Vessel Spasm • Hemorrhage • Access Site Complications/Hematoma • Thrombus/Thromboembolism • Allergic reaction • Vascular complication • Cardiac tamponade • Cardiac Perforation/Laceration • Conduction disorder • Embolism • Additional Surgical Procedure • Pericardial/pleural effusion • Sepsis/Infection/Inflammation • Foreign Body/Wire Fracture • Hemolysis • Hypovolemia • Myocardial Ischemia and/or Infarction • Stroke/Transient Ischemic Attack • Vessel Occlusion • Wire Entrapment/Entanglement • Valve Complication

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