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Transseptal access and pulmonary vein isolation via internal jugular veins for persistent atrial fibrillation treatment in a patient with left atrial isomerism, sinus node dysfunction and interrupted inferior vena cava: The usefulness of robotic magnetic navigation

INTRODUCTION

- This case report describes successful pulmonary vein isolation (PVI) for persistent atrial fibrillation in a patient with interrupted inferior vena cava (IVC) and sinus node dysfunction associated with left atrial (LA) isomerism.

METHODS

Case summary

- Initial attempt for LA access using the Agilis™ NxT Steerable Sheath (Abbott) through the femoral vein failed due to difficult catheter manipulation and cardiac visualization.
- Post-procedural magnetic resonance imaging (MRI) revealed IVC interruption.
- A second attempt was planned from the superior approach using the internal jugular (IJ) veins.

Transseptal access

- Left IJ vein access was used to introduce an intracardiac echocardiography (ICE) catheter into the mid-right atrium.
- The 8.5Fr **SupraCross™** Radiofrequency (RF) System* (Baylis Medical†) was introduced through the right IJ vein under fluoroscopic and ICE guidance.
- The **SupraCross™** Steerable Sheath was advanced towards the tricuspid annulus posteriorly and deflected to position the tip leftward and anterior (i.e. 10 o'clock position from operator's view).
- The sheath was then rotated counterclockwise, pulled back approximately 2 cm to position the tip leftward and posterior (i.e. 8 o'clock position) onto the fossa ovalis.
- Sufficient tenting of the septum was confirmed on ICE prior to transseptal puncture using the RF wire system*.
- The **SupraCross™** Sheath was advanced into the left atrium for subsequent ablation.

Radiofrequency ablation

- 3D electroanatomic mapping (CARTO®3, Biosense Webster) and Stereotaxis® Robotic Magnetic Navigation were used for catheter guidance.
- High power (45W) bilateral wide-area circumferential ablation was performed using the Thermocool® RMT (Biosense Webster) Catheter.

RESULTS

- Transseptal puncture using the RF wire system* was successful on the first attempt, without complications.
- PVI was achieved with no difficulties in catheter manipulation, procedural complications, or recurrence of symptoms after six months of follow-up.

DISCUSSION AND CONCLUSIONS

- The **SupraCross™** Steerable Sheath enabled angle correction from the IJ approach to optimize position on the fossa ovalis and tenting of the interatrial septum.
- Dedicated RF transseptal devices improve crossing success and reduce procedure time compared to mechanical needles, especially from an unconventional approach.
- Other techniques using a fixed curve sheath and Brockenbrough needle require manual curving in order to achieve a similar trajectory through the septum as a femoral approach, as well as mechanical force to puncture.

* The article was published as using the **TorFlex™** Steerable Guiding Sheath and **NRG™** Transseptal Needle. In actual fact, authors used the **SupraCross™** RF Solution (Baylis Medical†) for left atrial catherization, including the **SupraCross™** Steerable Sheath and pigtail **SupraCross™** RF Wire.

† A wholly-owned subsidiary of Boston Scientific Corporation.

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 the 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

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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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