Highlights from:
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Fluoroless Left Atrial Access for Radiofrequency and Cryoballoon Ablations using a Novel Radiofrequency Transseptal Wire

HIGHLIGHTS

- The **VersaCross™ RF Transseptal Solution** can enable fluoroless transseptal puncture in ablation procedures.
- Efficient procedure with average transseptal puncture time under 20 minutes.
- Zero exchanges required for transseptal puncture.

INTRODUCTION

- Procedure efficiency and transseptal puncture (TSP) remain a barrier to the full adoption of fluoroless procedures to reduce radiation exposure and associated health risks.
- This study reports the first clinical experience using the **VersaCross™ RF Transseptal Solution** (Baylis Medical*) for more efficient left atrial (LA) access through reduced device exchanges to facilitate fluoroless radiofrequency ablation (RFA) and cryoballoon ablation (CBA).

METHODS

- Fluoroless RFA and CBA procedures at two centers were retrospectively evaluated for procedural efficiency and safety.
- The **VersaCross™ RF Transseptal Solution**, consisting of a transseptal sheath, shapeable dilator, and RF wire (J-tip or pigtail), was used to cannulate the superior vena cava (SVC), perform RF TSP, and deliver RF ablation or the FlexCath Advance™ Steerable Sheath (Medtronic) in CBA.
- The **VersaCross™ RF Transseptal Solution** was visualized without fluoroscopy using:
  A. Electroanatomic mapping (EAM) using the **DuoMode™ Cable** (Baylis Medical) and EnSite Precision™ Cardiac Mapping System (Abbott), and intracardiac echocardiography (ICE).
  B. ICE only.
- RFA or CBA procedures were then performed as per usual protocol.

RESULTS

- 126 patients underwent RFA (n=72) or CBA (n=54) for left-sided cardiac arrhythmias.
- Fluoroless TSP was successful in 100% of cases regardless of septal anatomy. Device exchanges were not required for TSP or repositioning on the septum.
- All procedures were 100% successful without any intraprocedural complications.
- Average procedure time was 104.4 ± 38.0 min for RFA and 91.1 ± 22.1 min for CBA.
- Transseptal Puncture Time (Figure 1)
  - 2.8 ± 1.0 min for RFA and 3.5 ± 1.6 min for CBA from **VersaCross™ RF Wire** insertion into femoral introducer.
  - 14.5 ± 6.6 min for RFA and 19.2 ± 11.7 min for CBA from initial vascular access.

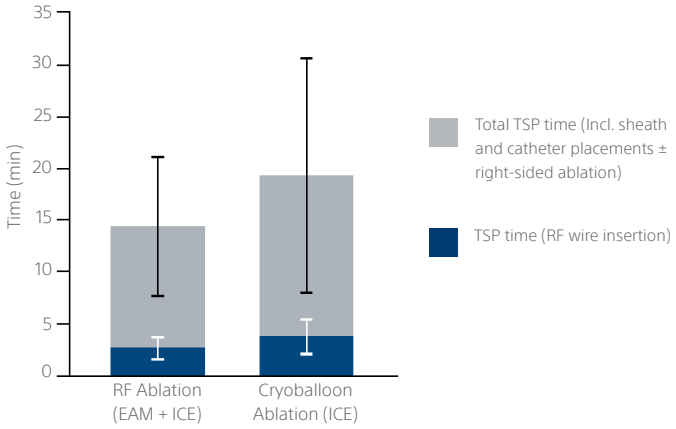

Figure 1. Transseptal puncture time during RF ablation (EAM + ICE) and cryoballoon ablation (ICE) using the **VersaCross™ RF Transseptal Solution** (Baylis Medical).

DISCUSSION & CONCLUSIONS

- RFA and CBA can be performed safely using the **VersaCross™ RF Transseptal Solution** without the use of fluoroscopy or lead.
- The **VersaCross™ RF Transseptal Solution** enabled more efficient and faster catheter ablation procedures compared to conventional techniques by:
  - Effective fluoroless visualization using EAM and/or ICE.
  - Reducing the number of device exchanges for LA access.
- TSP time with fluoroless visualization of the **VersaCross™ RF Wire** are comparable to fluoroscopy-guided TSP using RF wire, suggesting fluoroless visualization does not compromise TSP efficiency.[1]

[1]Sayah N., et al. Initial clinical experience with VersaCross transseptal system for transcatheter mitral valve repair. *Catheter Cardiovasc Interv*. 2021;97(6): 1230-4. https://doi.org/10.1002/ccd.29365.

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Brief Summary | **VersaCross™** 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 VersaCross™ RF Wire is indicated for creation of an atrial septal defect in the heart.

CONTRAINDICATIONS: The VersaCross™ 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 Baylis 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 VersaCross™ 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 VersaCross™ 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 VersaCross™ 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 VersaCross™ RF Wire. Attempts to use it with other RF Generators and devices can result in electrocution of the patient and/or operator. • The VersaCross™ 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 VersaCross™ RF Wire or accessory devices and may cause patient injury. • The VersaCross™ RF Wire has only been validated for transseptal puncture use through VersaCross™ dilators which have been demonstrated to provide the required support for optimal function. • The VersaCross™ 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 VersaCross™ 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. • Careful manipulation of the VersaCross™ RF Wire must be performed to avoid vessel trauma. If resistance is encountered, DO NOT use excessive force to advance or withdraw the VersaCross™ 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. • The Baylis RF Generator is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the VersaCross™ 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. • If using electroanatomical mapping guidance, it is recommended to use it along with alternative imaging modality in the event there is loss of visibility of the device.

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

EP-1504711-AA

Brief Summary | **VersaCross™** Transseptal Dilator

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 VersaCross™ Transseptal Dilator 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 VersaCross™ Steerable Sheath kit is intended for single patient use only. Do not attempt to sterilize and reuse the VersaCross™ Steerable Sheath kit. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. Failure to follow this instruction may result in patient complications • Maintain continuous hemodynamic monitoring throughout procedure • Provide continuous heparinized saline infusion while the introducer remains in vessel.

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.

ADVERSE EVENTS: Adverse events that may occur while using the VersaCross™ 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 • Thromboembolic events • Stroke • Valve damage • Myocardial infarction • Pacemaker/defibrillator lead displacement • Pulmonary edema • Coronary artery spasm and/or damage • Vessel trauma • Pericardial/pleural effusion

EP-1506213-AA

Brief Summary | **VersaCross™** Transseptal 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 VersaCross™ Transseptal Sheath kit is used for the percutaneous introduction of various types of cardiovascular catheters and guidewires to all heart chambers, including the left atrium via transseptal perforation/puncture.

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 use of echocardiography is recommended. • The VersaCross™ Transseptal Sheath kit is intended for single patient use only. Do not attempt to sterilize and reuse the VersaCross™ Transseptal Sheath kit. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another. • Do not attempt direct percutaneous insertion of the sheath without the dilator as this may cause vessel injury. • Careful manipulation must be performed to avoid cardiac damage or tamponade. Sheath advancement should be done under fluoroscopic guidance. Echocardiographic guidance is also recommended.

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. • The VersaCross™ Transseptal Sheath is compatible with introducer sheaths 11Fr or larger. • The VersaCross™ Transseptal Sheath and Dilator are compatible with transseptal devices and guidewires .035" or smaller. • The VersaCross™ Transseptal Sheath kit is NOT compatible with transseptal needles such as the "NRG™ Transseptal Needle".

ADVERSE EVENTS: Adverse events that may occur while using the VersaCross™ Transseptal Sheath kit include: • Infection • Air embolus • Local nerve damage • Hemorrhage • Embolic events • Vessel spasm • AV fistula formation • Atrial septal defect • Pseudoaneurysm • Perforation and/or tamponade • Arrhythmias • Pericardial/pleural effusion • Hematoma • Vessel trauma • Valve damage • Catheter entrapment

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