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Randomized comparison of a radiofrequency wire versus a radiofrequency needle system for transseptal puncture

HIGHLIGHTS

- RF wire-based transseptal technique resulted in a faster time to transseptal puncture, with fewer equipment exchanges, compared to an RF-needle-based workflow.

INTRODUCTION

- The overall efficiency and safety of many electrophysiology and structural interventions are dependent on the success of the transseptal puncture (TSP), which can be improved using radiofrequency (RF) energy.
- The **VersaCross**™ RF solution (Baylis Medical*) system uses a single RF wire to position the TSP assembly into the superior vena cava (SVC), perform RF TSP, and then lead the TSP assembly into the left atrium (LA), eliminating the need for a transseptal needle and wire/needle exchange.
- The WIRE-IT (**W**ire **I**nstrumentation with **R**F **E**nergy to **I**mpact **T**SP) is a randomized controlled trial comparing the use of a standard needle-based workflow to the **VersaCross**™ wire based-workflow in patients undergoing left atrial catheter ablation.

METHODS

- Single-center single-blinded randomized trial comparing efficacy and safety of two TSP workflows:
  - **NRG**™ needle-based workflow: TSP was performed using an **NRG**™ transseptal needle (Baylis Medical*) with an Agilis™ NXT (Abbott) or Vizigo™ (Biosense Webster) steerable sheath. In some cases, a second TSP was performed using a separate **NRG**™ transseptal needle with an SL1™ sheath (Abbott).
  - **VersaCross**™ wire-based workflow: TSP performed using a **VersaCross**™ pigtail RF transseptal wire with a **VersaCross**™ **Steerable Sheath**. A second TSP was performed using the same RF wire and an 8.5F fixed curve **VersaCross**™ **Transseptal Sheath**.
- **Primary outcome:** Time to first TSP from wire insertion to removal of the dilator and transseptal needle or wire after LA access.
- **Secondary outcome:** Times to second and combined TSP, TSP fluoroscopy time, number of equipment exchanges, and complications.

RESULTS

- 75 patients underwent TSP using either the **NRG**™ needle-based workflow (n=36) or the **VersaCross**™ wire-based workflow (n=39).
- Double TSP was performed in 83% of participants in the needle workflow group vs. 90% in the wire workflow group (p=0.41). Device exchanges were not required for TSP or repositioning on the septum.
- The wire-based workflow resulted in 25% shorter time to first TSP compared to the needle-based workflow (p=0.03, Figure 1A).
- 29% shorter time to second TSP (median 6.0 [IQR: 4.9-7.8] min vs. 8.4 [IQR: 5.5-13.4] min, p=0.04) and 32% shorter combined TSP time (p=0.007) in the wire-based workflow compared to needle-based workflow (Figure 1B).
- Lower trend (30%, p=0.06) for overall TSP fluoroscopy time for the wire-based workflow vs. the needle-based workflow (Figure 1C).
- More equipment exchanges in the needle-based workflow (one) compared to the wire-based workflow (none) for first TSP; 28% of needle-based workflow patients required two or more exchanges on the first TSP.
- No complications in the wire-based workflow compared to one transient ventricular asystole due to atrioventricular (AV) block in the needle-based workflow (mechanical injury to the AV node caused by the steerable sheath).

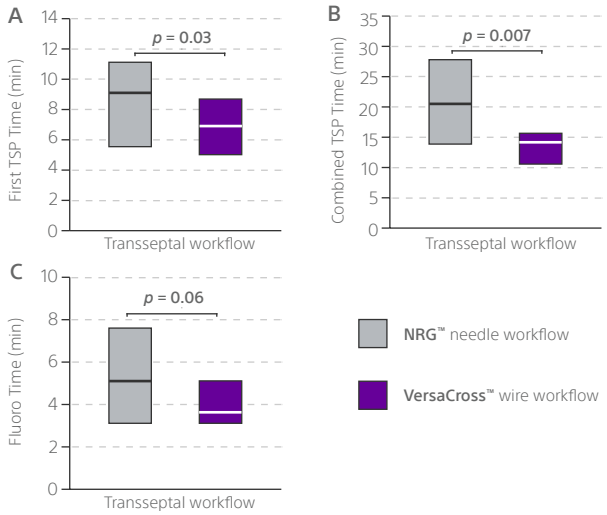

Figure 1. Outcomes following randomization to **NRG**™ needle-based workflow or **VersaCross**™ wire-based workflow in patients undergoing double TSP for left atrial catheter ablation. A) First TSP time, B) Combined TSP time, C) Overall fluoroscopy time. Values are the median ± interquartile range (IQR).

DISCUSSION & CONCLUSIONS

- **VersaCross**™ wire-based workflow resulted in shorter time to TSP and fewer device exchanges, eliminating guidewire removal, sheath flushing, and needle insertion after positioning in SVC.
- **VersaCross**™ wire-based workflow allowed easy repositioning for TSP assembly without rewiring to optimize TSP location.
- TSP procedural variability was limited with **VersaCross**™ wire-based workflow (smaller IQRs) resulting in a more consistent experience and an overall positive procedural efficiency.

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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

EP-1506605-AA

Brief Summary | **VersaCross™** 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 VersaCross™ 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 use of echocardiography is recommended. • 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. • Do not attempt direct percutaneous insertion of the sheath without the dilator as this may cause vessel injury. • Maintain continuous hemodynamic monitoring throughout procedure • Provide continuous heparinized saline infusion while the introducer remains in vessel. • 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 VersaCross™ Steerable 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™ 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 • Pericardial/pleural effusion • Pulmonary edema • Coronary artery spasm and/or damage • Vessel trauma • Pacemaker/defibrillator lead displacement

EP-1506705-AA

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