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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).

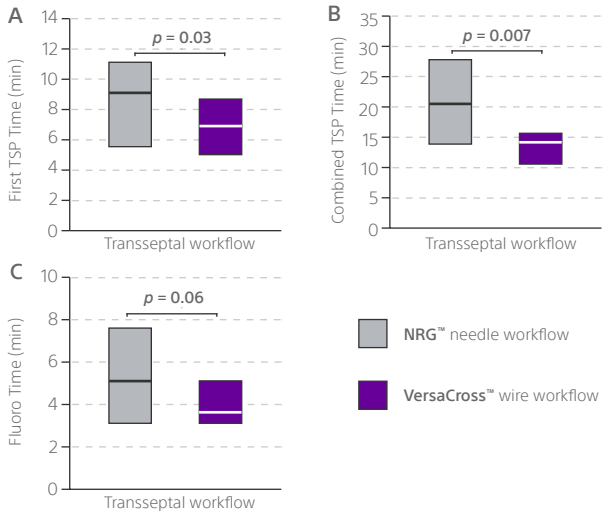

Figure 1. Outcomes following randomization to **NRG**™ needle-based workflow or **VersaCross**™ wire-based workflow in patients undergoing double TSP for left atrial catheter ablation. A) First TSP time, B) Combined TSP time, C) Overall fluoroscopy time. Values are the median ± interquartile range (IQR).

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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VersaCross™ RF Wire

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner. Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions. **INTENDED USE/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. **In the EU:** The VersaCross RF Wire is not intended for use with neonatal patients that are less than one month of age. **WARNINGS:** • Only physicians with a thorough understanding of angiography and percutaneous interventional procedures should use this device. It is recommended that physicians avail themselves of pre-clinical training, a review of pertinent literature and other appropriate education before attempting new interventional procedures. • The VersaCross RF Wire and Connector Cable are supplied STERILE using an ethylene oxide process. Do not use if the package is damaged. • 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 active tip and distal curve of the VersaCross RF Wire are fragile. Be careful not to damage the tip or the distal curve while handling the VersaCross RF Wire. If the tip or the distal curve becomes damaged at any time during its use, discard the VersaCross RF Wire immediately. Do not attempt to straighten the active tip if bent. Damage to device can lead to patient injury. • 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. • Do not attempt to insert or retract the VersaCross RF wire through a metal cannula or a percutaneous needle, which may damage the device and may cause patient injury. **PRECAUTIONS:** • Do not attempt to use the VersaCross RF Wire and the Connector Cable before thoroughly reading the accompanying Instructions for Use. • RF puncture procedures should be performed only by physicians thoroughly trained in the techniques of RF-powered puncture in a fully equipped catheterization laboratory. • The sterile packaging should be visually inspected prior to use. Do not use the devices if the packaging has been damaged or compromised. • Visually inspect the VersaCross RF Wire and Connector Cable prior to use to ensure there are no cracks or damage to the insulating material. Do not use the wire or the cable if there is any damage. • Do not use the VersaCross RF Wire and/or Connector Cable after the use-by date indicated on the label. • The VersaCross RF Wire and Connector Cable are intended for use with only those devices listed in Section VIII, Equipment Required. • Read and follow the manufacturer's Instructions For Use for the DIP electrode. Always use DIP electrodes that meet or exceed IEC 60601-2-2 requirements. • Placement of the DIP electrode on the thigh could be associated with higher impedance. • In order to prevent the risk of ignition, ensure that flammable materials are not present in the room during RF power application. • Take precautions to limit the effects that the electromagnetic interference (EMI) produced by the Baylis RF Generator may have on the performance of other equipment. Check the compatibility and safety of combinations of other physiological monitoring and electrical apparatus to be used on the patient in addition to the Baylis RF Generator. • Adequate filtering must be used to allow continuous monitoring of the surface electrocardiogram (ECG) during RF power applications. • Do not attempt to insert and use the proximal end of the VersaCross RF Wire as the active tip. • Do not bend the VersaCross 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 VersaCross RF Wire and Connector Cable. • 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. • VersaCross RF Wire and ancillary sheath and/or dilator assembly advancement should be done under imaging guidance. The use of visible markers on the wire body are only an approximate guide for positioning the wire tip with the distal end of the dilator. • Do not attempt to deliver RF energy until the active tip of the VersaCross RF Wire is confirmed to be in good contact with the target tissue. • Avoid RF energy delivery of the VersaCross RF Wire with incompatible dilator or cannula devices, which may lead to patient burns, ineffective puncture or failure to puncture. • It is recommended not to exceed five (5) RF power applications per VersaCross RF Wire. • Never disconnect the Connector Cable from the Baylis RF Generator while RF power is being delivered. • Never disconnect the Connector Cable from the Baylis RF Generator by pulling on the cable. Failure to disconnect the cable properly may result in damage to the cable. • Do not twist the Connector Cable while inserting or removing it from the Isolated Patient Connector on the Baylis RF Generator. Twisting the cable may result in damage to the pin connectors. • 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. • Apparent low power output or failure of the equipment to function properly at normal settings may indicate faulty application of the DIP electrode, failure to an electrical lead, or poor tissue contact at the active tip. Check for obvious equipment defects or misapplication. Attempt to better position the active tip of the VersaCross RF Wire against the atrial septum. Only increase the power if low power output persists. • 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. **POTENTIAL 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/pleural effusion • Tachycardia • Vascular Trauma • Additional Surgical Procedure • Wire entrapment/ entanglement • Foreign body/wire fracture

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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. • The VersaCross Transseptal Sheath kit is supplied STERILE using an ethylene oxide process. Do not use if the package is damaged. • The sheath's shaft is coated with a lubricious coating. The following warnings must be considered: o Use of the sheath with introducer sheaths smaller than the size listed in the section below may result in a tight fit that affects device performance, including coating integrity. o Excessive wiping and/or wiping of the sheath with a dry gauze may damage the coating. o Manual shaping of the sheath distal curve shall be done with smooth motions along the curve without applying excessive pressure. Excessive manual bending and/or shaping of the sheath shaft may affect the coating integrity. • Care should be taken to ensure that all air is removed from the sheath before infusing through the side port. • Care should be taken when inserting or removing the dilator and catheters from the sheath. • Do not attempt direct percutaneous insertion of the sheath without the dilator as this may cause vessel injury. • Damage to guidewire may result if withdrawn through a metal needle cannula. • Careful manipulation must be performed to avoid cardiac damage or tamponade. Sheath advancement should be done under fluoroscopic guidance. Echocardiographic guidance is also recommended. • The Mechanical Guidewire is coated with a lubricious coating. The following warnings must be considered: o Use with incompatible introducers or dilators may affect device performance and integrity, including coating integrity o Excessive manual bending and/or shaping of the device may affect the coating integrity. **PRECAUTIONS:** • Do not attempt to use the VersaCross Transseptal Sheath kit before thoroughly reading the accompanying Instructions for Use. • 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 sterile packaging and sheath should be visually inspected prior to use. Do not use the device if it has been compromised or damaged. • Only physicians thoroughly trained in the techniques of the approach to be used should perform interventional procedures. • Only physicians or personnel trained in aseptic techniques should perform aseptic presentation. • Note product "Use By" date. • 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 "NRGTM Transseptal Needle". • Do not reshape 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. • Only use compatible tip straighteners with the guidewire. • Do not attempt to insert the proximal end of the guidewire as the distal end. • Confirm ancillary devices are compatible with the dilator and guidewire diameters before use. • Individual patient anatomy and physician technique may require procedural variations. • Do not attempt to use the guidewire with electrocautery tools. • Avoid guidewire contact with liquids other than blood, isopropyl alcohol, contrast solution or saline. **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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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. • Care should be taken to ensure that all air is removed from the sheath before infusing through the side port. • Care should be taken when inserting or removing the dilator and catheters from the sheath.• 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. • To minimize vacuum effects during withdrawal, remove components/aspirate slowly. Refrain from aspiration if a wire is directly through the valve. • Avoid contact with liquids other than blood, isopropyl alcohol, contrast solution or saline. • Prior to steerable sheath's delivery and removal, ensure distal section is as straight as possible. • Do not kink, stretch or severely bend steerable sheath. • Do not use surgical instruments to handle sheath. • The sheath device shaft in its entirety is coated with a hydrophobic lubricious coating for smoother device manipulation. The following warning must be considered: o Excessive wiping and/or wiping with a dry gauze may damage the coating. • The guidewire is coated with a lubricious coating. The following warnings must be considered: o Use with incompatible introducers or dilators may affect device performance and integrity, including coating integrity. o Excessive manual bending and/or shaping of the device may affect the coating integrity. • 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:** • Do not attempt to use the VersaCross Steerable Sheath kit before thoroughly reading the accompanying Instructions for Use. • 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 Steerable Sheath kit is supplied STERILE using an ethylene oxide process. • The sterile packaging and all components should be visually inspected prior to use. Do not use if the device, packaging or sterile barrier have been compromised or damaged. • Only physicians thoroughly trained in the techniques of the approach to be used should perform interventional procedures. • Do not use device after its "Use By" date. • 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 "NRGTM Transseptal Needle". • Do not reshape 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. • Only use compatible tip straighteners with the guidewire. • Do not attempt to insert the proximal end of the guidewire as the distal end. • Confirm ancillary devices are compatible with the dilator and guidewire diameters before reuse. • Individual patient anatomy and physician technique may require procedural variations. • Do not attempt to use the guidewire with electrocautery tools. • Avoid guidewire contact with liquids other than blood, isopropyl alcohol, contrast solution or saline. **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

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