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 (Wire Instrumentation with RF Energy to Impact TSP) 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™ pigtails 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).

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.
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 RF delivery systems.

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 these devices.

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 its accessories, 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 events • Vessel perforation • Atrial Fibrillation • Myocardial Infarction • Vessel spasm • Sustained arrhythmias • Acute Fluff • Hemorrhage • Vascular thrombus • Perforation of the myocardium • Hematoma • Allergic reactions to contrast media • Ventricular fibrillation • Pain and tenderness • Astrocytoma • Pericardial effusion • Tachycardia • Vascular Trauma • Additional Surgical Procedure • Wire entanglement/entanglement • Foreign body/wire fracture

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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 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™ Steerable Sheath kit. Nace 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. • 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. Nace 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.

ADVERSE EVENTS: Adverse events that may occur while creating an atrial septal defect include: • Tamponade • Sepsis/Infection • Thromboembolic events • Vessel perforation • Atrial Fibrillation • Myocardial Infarction • Vessel spasm • Sustained arrhythmias • Acute Fluff • Hemorrhage • Vascular thrombus • Perforation of the myocardium • Hematoma • Allergic reactions to contrast media • Ventricular fibrillation • Pain and tenderness • Astrocytoma • Pericardial effusion • Tachycardia • Vascular Trauma • Additional Surgical Procedure • Wire entanglement/entanglement • Foreign body/wire fracture

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 puncture/percuture.

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. Nace 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.

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. • 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. Nace 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.

ADVERSE EVENTS: Adverse events that may occur while creating an atrial septal defect include: • Tamponade • Sepsis/Infection • Thromboembolic events • Vessel perforation • Atrial Fibrillation • Myocardial Infarction • Vessel spasm • Sustained arrhythmias • Acute Fluff • Hemorrhage • Vascular thrombus • Perforation of the myocardium • Hematoma • Allergic reactions to contrast media • Ventricular fibrillation • Pain and tenderness • Astrocytoma • Pericardial effusion • Tachycardia • Vascular Trauma • Additional Surgical Procedure • Wire entanglement/entanglement • Foreign body/wire fracture

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