

## Highlights from:

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Yap et al., Catheter Cardiovascular Intervention Oct 2019 DOI: 10.1002/ccd.28548

# Transseptal access for left heart structural interventions in the setting of prior atrial septal defect closure

## INTRODUCTION

- ▶ Precise interatrial septum puncture is required for many left sided structural heart procedures.
- ▶ Atrial septal defect (ASD)/patent foramen ovale closure devices may impact procedural success.
- ▶ This article describes a technique for planning and performing MitraClip™ (Abbott Vascular) and WATCHMAN™ (Boston Scientific) procedures in patients with an AMPLATZER™ Atrial Septal Occluder (ASO) device (Abbott Vascular).

## METHODS

### Imaging

- ▶ Preprocedural cardiac-gated multidetector computed tomography (MDCT) was used to delineate margins of the ASD closure device relative to the septum in the bicaval, short axis, and four chamber view to identify transseptal puncture location.
- ▶ Intraprocedural fluoroscopy, transesophageal echocardiography (TEE), and/or intracardiac echocardiography (ICE) were used to guide transseptal puncture.

### Case 1: MitraClip™

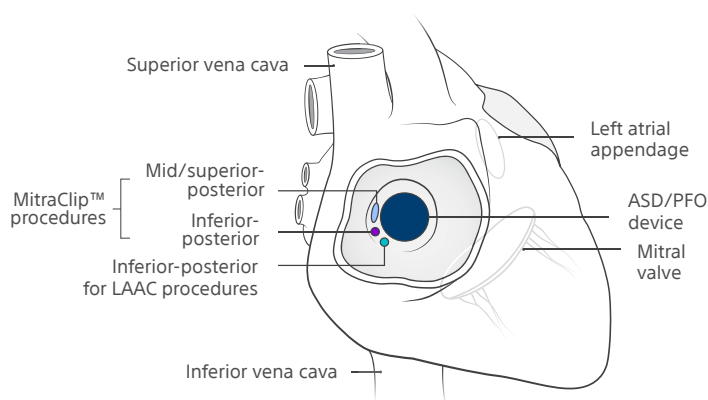
- ▶ TEE and fluoroscopy were used to position the transseptal assembly inferoposteriorly away from the 22-mm ASO, and confirm adequate tenting and transseptal height.
- ▶ Transseptal puncture was performed using a radiofrequency (RF) needle (Baylis Medical\*) and SL1™ Transseptal Sheath (Abbott Vascular).
- ▶ A Cook extra stiff wire positioned in the left superior pulmonary vein was used to exchange the transseptal sheath for the MitraClip™ Guiding Catheter.
- ▶ The procedure was continued as per standard protocol without interactions with the ASO.
- ▶ No treatment was required for a small iatrogenic atrial septal defect (iASD) with left-to-right shunting at the end of the procedure.
- ▶ No residual flow through the iASD was found at one year post-procedure.

### Case 2: Left atrial appendage closure (LAAC)

- ▶ In addition to fluoroscopy and TEE, ICE was used to visualize the inferior aspect of the fossa ovalis prior to transseptal puncture using the Baylis\* RF needle and SL1™ Sheath.
- ▶ Due to space limitation on the septum below the 18-mm ASO, the **ProTrack™** Pigtail Wire (Baylis Medical\*) was used to obtain left atrial (LA) access for the WATCHMAN™ Sheath.
  - The **ProTrack™** Wire allowed oscillating rotation to overcome resistance against the ASO as the sheath was advanced into the LA
- ▶ The procedure continued and a 27-mm WATCHMAN™ device was deployed without challenges.
- ▶ 6-week post-procedural TEE showed adequate device seating and no iASD.

## DISCUSSION AND CONCLUSIONS

- ▶ Transseptal puncture for structural heart procedures is possible in the presence of ASO devices.
- ▶ Multimodality imaging (e.g. MDCT, TEE, ICE, and fluoroscopy) can be used to assess space on the interatrial septum, identify alternative sites, and guide transseptal puncture.
- ▶ Extra stiff support wires should be considered when advancing large-bore sheaths with resistance against the ASO.



**Figure 1.** The relative location of cardiac structures to the interatrial septum provides a rationale for transseptal puncture location for MitraClip™ and LAAC procedures.

## Brief Summary | NRG™ Transseptal Needle

**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 NRG™ Transseptal Needle is used to create an atrial septal defect in the heart. Secondary indications include monitoring intracardiac pressures, sampling blood, and infusing solutions.

**CONTRAINDICATIONS:** The NRG™ Transseptal Needle is not recommended for use with any conditions that do not require cutting or coagulation of soft tissue.

**WARNINGS:** • Laboratory staff and patients can undergo significant X-ray exposure during radiofrequency 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 NRG™ Transseptal Needle is intended for single patient use only. Do not attempt to sterilize and reuse the needle. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. Failure to do so may result in patient complications. • The NRG™ Transseptal Needle must be used with the BMC Connector Cable. Attempts to use it with other connector cables can result in electrocution of the patient and/or operator.

**PRECAUTIONS:** • Placement of the dispersive electrode on the thigh or hip could be associated with higher impedance. • In order to prevent the risk of ignition make sure that flammable material is not present in the room during RF power application. • Careful needle manipulation must be performed to avoid cardiac damage, or tamponade. Needle advancement should be done under image guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the needle. • During power delivery, the patient should not be allowed to come in contact with ground metal surfaces. • Thoroughly flush the NRG™ Transseptal Needle with heparinized saline solution prior to use. • If using electroanatomical mapping guidance it is recommended to confirm tip placement on the fossa ovalis and septal tenting before RF puncture with graphic imaging or another imaging modality.

**ADVERSE EVENTS:** Adverse events that may occur while using the Baylis Medical Radiofrequency Puncture System 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 • Thermal damage to tissue • Arteriovenous fistula • Pericardial Effusion

EP-1506305-AA

## Brief Summary | ProTrack™ Pigtail 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 ProTrack™ Pigtail Wires are intended for use in percutaneous transseptal procedures to introduce and position catheters and other interventional devices within the left heart. The device is not intended for use in the coronary arteries.

**CONTRAINDICATIONS:** There are no known contraindications for this device.

**WARNINGS:** • DO NOT push, auger, withdraw or torque a pigtail wire against resistance until the cause of the resistance has been determined. Applying excessive force against unexpected resistance may cause damage to the pigtail wire, interventional device and/or vessel/organ. • When the pigtail wire is exposed to the vascular system, it should be manipulated while under high-resolution imaging guidance including fluoroscopy and/or echocardiography. Improper visualization of the guidewire may lead to misplacement, dissection, or perforation. • Inspect the pigtail wire prior to use for coil separation, kinking, appropriate distal tip flexibility or breakage. If the pigtail wire is damaged or defective, do not use it. Using a damaged or defective pigtail wire may cause vasculature damage and/or compromise pigtail wire performance. • Laboratory staff and patients can undergo significant X-ray exposure during interventional procedures due to the continuous usage of fluoroscopic imaging. The 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.

**ADVERSE EVENTS:** Potential complications associated with the use of the pigtail wire include, but are not limited to: • Vessel Perforation/Dissection/Trauma or Damage • Vessel Spasm • Hemorrhage • Access Site Complications/Hematoma • Thrombus/Thromboembolism • Allergic reaction • Vascular complication • Cardiac tamponade • Cardiac Perforation/Laceration • Conduction disorder • Embolism • Additional Surgical Procedure • Pericardial/pleural effusion • Sepsis/Infection/Inflammation • Foreign Body/Wire Fracture • Hemolysis • Hypovolemia • Myocardial Ischemia and/or Infarction • Stroke/Transient Ischemic Attack • Vessel Occlusion • Wire Entrapment/Entanglement • Valve Complication

EP-1515204-AA

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EP-1580104-AA