ICE-Guided Implantation of the Conformal Left Atrial Appendage Closure Device: First Clinical Report

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Introduction

- Left Atrial Appendage Closure (LAAC) is emerging as a cornerstone AF stroke reduction strategy in patients that are poor candidates for long-term oral anticoagulation.
- Acceptance of LAAC is limited by the need for procedural TEE and consequently, the requisite general anesthesia.
- The Conformal LAAC device (Conformal Medical, Inc.) is a novel LAAC implant composed of a foam cup/nitinol endoskeleton and designed to provide an improved seal necessitating less precise positioning (Figure 1).
- We evaluated the ability to perform LAAC with a combination of intracardiac echo (ICE) and fluoroscopy, and specifically without TEE or GA.

Figure 1. *Conformal Left Atrial Appendage Closure Device and Delivery System*

Methods

- For this Czech FIH clinical trial, both EC and Czech National Regulatory approval were obtained pre-enrollment. All patients signed informed consent.
- Key Inclusion criteria:
  1. Indicated / planned for LAAC
  2. Mean LAA diameter (ostial min + max size / 2) < 25 mm (because at that time, only 1 device size was available (a larger size able to accommodate large appendages has recently become available)
- Protocol for ICE-guided LAAC:
  1. Baseline TEE to exclude thrombus and obtain LAA measurements
  2. LAAC procedure performed under sedation
  3. ICE (Acunav, Siemens Inc) imaging: i) confirm no LAA thrombus (ICE in pulmonary artery), & ii) transseptal puncture w/ standard 8.5Fr sheath
  4. TS sheath exchanged for custom Delivery Sheath (15.4Fr ID/17.5Fr OD), but first maneuver ICE catheter into LA thru TS hole using wire as guide
  5. Deploy LAAC device with ICE guidance (from within LAA)
  6. Assess implant position, seal and stability using fluoroscopy and ICE
  7. Just prior to device release, introduce TEE probe to validate ICE
  8. Patients were discharged on DAPT.

Results

- Patient Cohort: n=8; 69.1±12.6 yrs, 63% female, CHA_2DS_2-Vasc = 3.9±1.9
- Broad range of LAA sizes: 19.9±2.0 mm, range 15-28 mm, min depth 13 mm
- ICE assessment revealed good position, and a small leak in only 1 pt
- Pre-release TEE: No leak in 7 pts (87.5%), Minor leak (<2mm) in 1 pt (12.5%)
- Implantation successful in all 8 pts (100%), using a single device/pt
- Procedure time = 45.4±10.7 min ; Fluoroscopy time = 4.6±1.5 min
- Pre-discharge TTEs (next day) were normal in all pts
- 45-day follow-up TEEs (completed in 5 of 8 pts): all devices were stable, no device thrombus, and 1 small leak (<2 mm; same pt with leak at baseline)
- Two adverse events (unrelated to both device and procedure):
  1. Pericardial effusion following removal of temporary RV pacing wire for bradycardia which occurred in a subsequent hospitalization.
  2. Hospitalization for tachyarrhythmia (treated with medications)

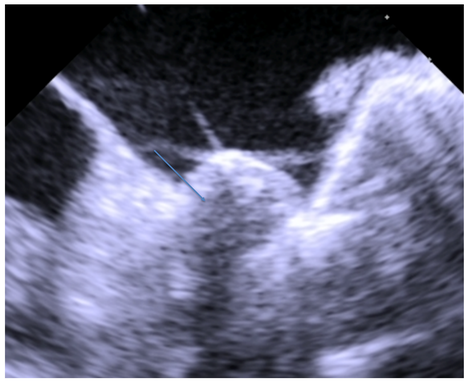

Figure 2. *ICE of Implant prior to release*

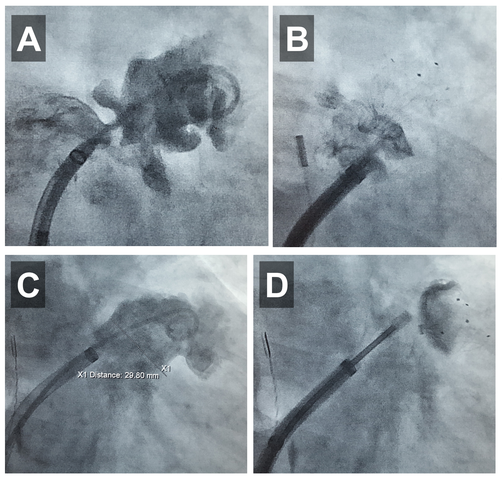

Figure 3. Fluoroscopy Imaging of ICE-guided LAA closure. The baseline contrast angiography images just prior to implantation are shown in **A** & **C**. Note that in post-implant videos (**B** & **D**), the device was occlusive, thereby preventing the contrast from moving into the LAA. Similarly, in **D**, some of the contrast was embedded into the foam covering.

Conclusions

In this first report of ICE-guided LAAC with the novel Conformal LAAC Implant, implantation was feasible, safe and effective in achieving 100% closure. Further study is required to fully validate this ICE-only (no TEE/no anesthesia) protocol.

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