Inter-atrial Septal Balloon Dilation to Facilitate Intracardiac Echocardiography Guided Left Atrial Appendage Occlusion

Sandeep Goyal[1], Ashish A. Bhimani[1], Danesh Kella[2], Anahita Tyagi[1], Venkateshwar Polsani[1], and Thomas Deering[1]

[1]Piedmont Heart Institute
[2]Mayo Clinic in Florida

March 10, 2024

Abstract

Background: Percutaneous left atrial appendage occlusion (LAAO) is traditionally performed under general anesthesia with trans-esophageal echocardiography guidance. Intracardiac echo (ICE) guided LAAO closure is increasing in clinical use. The ICE catheter is crossed into LA via interatrial septum (IAS) after the septum is dilated with LAAO delivery sheath. This step can be time-consuming and requires significant ICE catheter manipulation increasing the risk of cardiac perforation. Pre-emptive septal balloon dilation can potentially help with the advancement of ICE in LA. Objective: Evaluate the effect of pre-dilation of IAS with an 8 mm balloon on ease of crossing the ICE catheter, fluoroscopy time for crossing, and overall procedure time. Methods: The Piedmont LAAO registry was used to identify consecutive patients undergoing LAAO. The initial 25 patients where balloon dilation of IAS was performed served as the experimental cohort, and the 25 consecutive patients prior to that in whom balloon dilation was not performed, served as controls. For the experimental group, after a trans-septal puncture, the sheath was retracted to the right atrium with guide wire still in the LA. An 8x40 mm Evercoss over the wire balloon was inflated across the IAS. The ICE catheter was then crossed into the LA using the fluoroscopic landmark of the guide wire and the ICE imaging. The sheath was then advanced along the ICE catheter via the transseptal puncture (TSP) and the procedure continued. Follow up CT imaging was obtained in 4-8 weeks. Results: Each group included 25 patients. There were no significant differences in baseline characteristics. All procedures were performed successfully with the use of conscious sedation and ICE guidance. There was a significant reduction in overall procedure time, fluoroscopy time, and time for trans-septal puncture to ICE in LA. There was no difference in the size of the acute residual interatrial shunt as measured via ICE or size and presence of iatrogenic ASD at follow up. Conclusion: Balloon dilation of TSP is safe and associated with increased efficiencies in ICE guided LAAO procedures.

Introduction:

Stroke prevention in atrial fibrillation (AF) typically necessitates either oral anticoagulation (OAC)[1] or, when OAC is not suitable, consideration for left atrial appendage occlusion (LAAO)[1]. Historically, percutaneous LAAO is performed under general anesthesia and is guided by trans-esophageal echocardiography (TEE) [2,3]The adoption of LAAO is expanding, owed to heightened procedural success and diminished complications[4] . A shift toward Intracardiac echo (ICE) guided LAAO is evident, aiming to optimize the procedure by negating the necessity for general anesthesia and TEE[5,6] [7]. However, optimal LAA imaging from right sided cardiac chambers remains challenging[8], necessitating ICE catheter placement in the LA. This can be achieved via a second trans-septal puncture or a singular puncture utilizing the "buddy" technique[6]. In the latter, the ICE catheter's LA traversal via the interatrial septum (IAS) follows IAS dilation with the LAAO delivery sheath[6],[9]. This can be prolonged and demands intricate ICE catheter adjustments, amplifying cardiac perforation risks. Existing solutions encompass balloon dilation or snare techniques post unsuccessful crossing attempts[6,10]. We hypothesized that preemptive septal balloon dilation may facilitate ICE introduction in the LA.

Our objective was to assess the impact of an 8 mm balloon pre-dilation of the IAS on the ease of ICE catheter crossing, fluoroscopy time, and overall procedural duration.

Materials & Methods:

This was a retrospective, observational cohort study based on a single-center prospective LAAO registry at Piedmont hospital, Atlanta, GA. The Study protocol was approved by the institutional IRB. The first 25 consecutive patients undergoing balloon dilation of IAS during LAAO served as the experimental cohort. The 25 consecutive patients prior to that in whom balloon dilation was not performed, served as controls.

Two separate venous accesses were obtained in the right femoral vein with 8.5 F Versacross sheath and 9-F 45-cm sheaths to accommodate the transeptal delivery system and the ICE catheter (AcuNav, Siemens healthcare), respectively. Full anticoagulation was administered before trans-septal puncture (TSP). An ICE positioned in the mid right atrium guided the TSP.

For the experimental group, post TSP, the 8.5 F Versacross sheath was retracted to the right atrium with the guide wire still in the LA. An 8x40 mm Evercross over the wire balloon was placed across the IAS. The balloon was inflated at nominal pressure for 1 min and retracted back into the sheath (Figure 1). The ICE catheter was then crossed into the LA using the fluoroscopic landmark of the guide wire and ICE imaging (Video 1). ICE imaging was used to decide on appropriate LAAO device and an LAAO sheath was chosen. The TSP sheath was then exchanged for the LAAO sheath, which was advanced along the ICE catheter via the TSP and the procedure continued. In the control group, the Versacross sheath was exchanged for the LAAO delivery sheath and septum was "flossed" with the LAAO sheath and the sheath was pulled to RA. ICE advancement was then attempted via the same TSP. Once the ICE catheter was in LA, the LAAO sheath was also advanced into the LA[6]. The rest of the procedure was performed in standard fashion. After completion of LAAO implant, the sheath and ICE catheter were brought to RA and the size of the atrial septal defect (ASD) was measured on 2D and color doppler echocardiography.

All patients underwent cardiac CT 4-8 weeks post procedure and the LAAO device was assessed for position and seal. Assessment was also made of any residual ASD and its size.

Descriptive statistics were used to analyze the data. Data are reported as

mean$\pm$ SD and median with interquartile range (IQR).

Results:

Each group included 25 patients. There were no significant differences in the baseline characteristics. All procedures were performed successfully with the use of conscious sedation and ICE guidance. There was a significant reduction in overall procedure time, fluoroscopy time, and time taken from trans-septal puncture to "ICE in LA". The overall procedure time was 54.5 $\pm$20.3 min in the conventional group vs 43.6 $\pm$ 4.7 min in the experimental group. The fluoroscopy time was 13.2 $\pm$11.2 min in the conventional group vs 6.1 $\pm$1.6 min in the experimental group. The transseptal puncture to ICE in LA time was 5.2 $\pm$7.5 min in the conventional group vs 2.9 $\pm$ 1.2 min in the experimental group (Table 1). There was no difference in the size of the acute residual interatrial shunt as measured via ICE. There were no acute procedural complications.

Imaging follow up was available on all patients. Timing of imaging was variable between 30-60 days. There was no difference in size of iatrogenic ASD in either group. There was one device related thrombus in control group and one patient with 2 mm peri device leak in the experimental group.

Discussion:

In this study, we present the outcomes of employing preemptive balloon-assisted dilation of the interatrial septum to facilitate the traversal of ICE in the Left Atrium during LAAO. While there have been isolated case reports describing the occasional utilization of this approach, our study stands as the first consecutive series that systematically compares this strategy against the conventional standard of care[11].

Our findings suggest that the routine use of preemptive balloon dilation of the IAS is correlated with an easier ICE traversal following a single trans-septal puncture. This approach significantly reduces both the total time required and the variability in the time needed to successfully navigate the ICE within the LA (2.9±1.2 minutes compared to 5.2±7.5 minutes).

With the availability of more than one LAAO device[10,12], the choice of device is often made post-assessment of the Left Atrial Appendage (LAA) during the procedure. However, opting for a large LAAO access sheath for IAS dilation necessitates an early decision regarding the device / sheath type before ICE traversal in the LA. As more LAAO devices gain approval, it becomes increasingly crucial to defer the device type selection until final imaging of the LAA can be performed via ICE within the operating suite. Our proposed approach effectively eliminates the need for unnecessary utilization of an inappropriate LAAO access sheath, thereby reducing costs and minimizing the number of device exchanges.

While Intracardiac Echocardiography (ICE) usage is on the rise for LAAO procedures, a significant majority of these procedures are still conducted under Transesophageal Echocardiography (TEE) guidance. The key challenges reported most frequently in the adoption of ICE for LAAO are the complexities associated with ICE traversal in the LA and obtaining clear views of the LAA with ICE. Our proposed strategy serves to expedite the learning curve for ICE traversal within the LA via a single trans-septal puncture, potentially lowering the barriers to early adoption of ICE in LAAO procedures.

Furthermore, the 4D ICE technology is increasingly available and being employed to guide LAAO procedures. However, these catheters typically possess larger diameters compared to their 2D counterparts[13] [14]. Our technique may prove particularly valuable in alleviating the challenges associated with ICE traversal in the LA when using these larger diameter 4D ICE catheters.

Finally, it is worth noting that ICE is the preferred modality for imaging during electrophysiologist (EP)-performed ablation procedures, enhancing the comfort level of EPs with ICE over Interventional cardiologists (ICs). However, this technique necessitates the use of large balloon catheters and other IC techniques. LAAO procedures are often performed by either EPs or ICs. Our approach highlights a unique opportunity for collaboration between electrophysiologists and interventional cardiologists, enabling a cohesive team to perform these procedures and fostering mutual learning.

Nevertheless, it is essential to acknowledge the limitations of this study. This research represents a single-center, single-operator investigation, which may limit the generalizability of the results. However, it is worth noting that we have reported data on consecutive patients undergoing LAAO outside of clinical trials. Additionally, we did not base the utilization of ICE or balloon dilation on any pre-imaging information.

Conclusion:

In conclusion, our study presents a strategy with promising implications for the field of LAAO procedures, offering enhanced efficiency, cost-effectiveness, and interdisciplinary collaboration. Further multi-center studies with multiple operators are warranted to validate these findings across diverse clinical settings and patient cohorts.

References:

1. January CT, Wann LS, Calkins H, et al.: 2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society in Collaboration With the Society of Thoracic Surgeons. Circulation 2019; 140:e125–e151.

2. Holmes DR, Kar S, Price MJ, et al.: Prospective randomized evaluation of the Watchman Left Atrial Appendage Closure device in patients with atrial fibrillation versus long-term warfarin therapy: the PREVAIL

trial. J Am Coll Cardiol 2014; 64:1–12.

3. Lakkireddy D, Thaler D, Ellis CR, et al.: Amplatzer Amulet Left Atrial Appendage Occluder Versus Watchman Device for Stroke Prophylaxis (Amulet IDE): A Randomized, Controlled Trial. Circulation 2021; 144:1543–1552.

4. Kar S, Doshi SK, Sadhu A, et al.: Primary Outcome Evaluation of a Next-Generation Left Atrial Appendage Closure Device: Results From the PINNACLE FLX Trial. Circulation 2021; 143:1754–1762.

5. Alkhouli M, Chaker Z, Alqahtani F, Raslan S, Raybuck B: Outcomes of Routine Intracardiac Echocardiography to Guide Left Atrial Appendage Occlusion. JACC: Clinical Electrophysiology 2020; 6:393–400.

6. Korsholm K, Jensen JM, Nielsen-Kudsk JE: Intracardiac Echocardiography From the Left Atrium for Procedural Guidance of Transcatheter Left Atrial Appendage Occlusion. JACC Cardiovasc Interv 2017; 10:2198–2206.

7. Jhand A, Thandra A, Gwon Y, et al.: Intracardiac echocardiography versus transesophageal echocardiography for left atrial appendage closure: an updated meta-analysis and systematic review. Am J Cardiovasc Dis 2020; 10:538–547.

8. Ho ICK, Neuzil P, Mraz T, et al.: Use of intracardiac echocardiography to guide implantation of a left atrial appendage occlusion device (PLAATO). Heart Rhythm 2007; 4:567–571.

9. Aguirre D, Pincetti C, Perez L, et al.: Single trans-septal access technique for left atrial intracardiac echocardiography to guide left atrial appendage closure. Catheter Cardiovasc Interv 2018; 91:356–361.

10. Kawsara A, Raybuck B: Snare and track (SNACK) technique: a novel approach for successful placement of an intracardiac echocardiogram catheter in the left atrium: a case report. Eur Heart J Case Rep 2022; 6:ytac365.

11. The Case for Intracardiac Echo to Guide Left Atrial Appendage Closure - ClinicalKey [Internet]. [cited 2023 Sep 30],. Available from: https://www.clinicalkey.com/#!/content/journal/1-s2.0-S2211745821001115

12. Ahmed A, Bawa D, Kabra R, et al.: Left Atrial Appendage Closure with Watchman vs Amulet Devices: Similarities and Differences. Curr Cardiol Rep 2023; 25:909–915.

13. Khalili H, Patton M, Taii HA, et al.: 4D Volume Intracardiac Echocardiography for Intraprocedural Guidance of Transcatheter Left Atrial Appendage Closure. J Atr Fibrillation 2019; 12:2200.

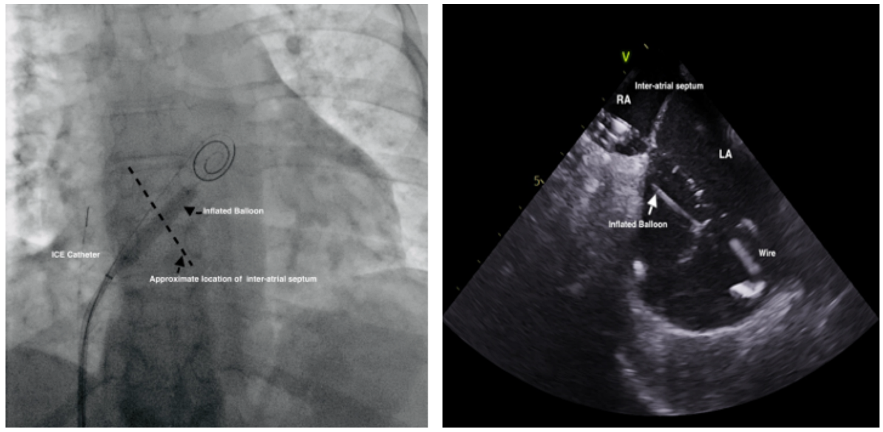
14. Kaplan RM, Narang A, Gay H, et al.: Use of a novel 4D intracardiac echocardiography catheter to guide interventional electrophysiology procedures. J Cardiovasc Electrophysiol 2021; 32:3117–3124.

Table 1

	Conventional Group (n=25)	Balloon Dilation Group (n=25)
Age (mean±SD)	79.3 (±7.9) yr	77.3(±10.1) yr
Sex- Female (%)	36%	44%
CHADS2-Vasc score (mean±SD)	4.3(±2.1)	4.6(±1.8)
Procedure time (minutes)	54.50 (± 20.3)	43.6 (±4.7)
Fluoroscopy time (minutes)	13.2 (±11.2)	6.1 (±1.6)
Trans-septal to ICE in LA time (minutes)	5.2(±7.5)	2.9 (±1.2)
Type of LAAO device (n)	Watchman FLX : 24 Amulet :1	Watchman FLX: 22 Amulet: 3
Interatrial septal shunt (mm)	5.6 (±1.6)	6.1(±1.3)
Interatrial Septal defect (mm)-1st imaging follow up	3.3 (± 1.1)	3.5 (±1.2)
Iatrogenic ASD present (n)	11	12

Table 1: Baseline and Procedural characteristics of two groups.

Figure and Video Legends:



Panel 1 : Fluoroscopy

Panel 2 : Intracardiac Echocardiography

Figure 1: Panels showing Dilation of interatrial septum on fluoroscopy and intracardiac echocardiography

Video 1 : Intracardiac echocardiography catheter crossing from right to left atrium after balloon dilation