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BEST PRACTICES FOR INTEGRATING CONCOMITANT LAAC AND AF ABLATION PROCEDURES IN CLINICAL CARE

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CV BUSINESS WHITE PAPER

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EXECUTIVE SUMMARY

The concomitant performance of atrial fibrillation (AF) ablation and left atrial appendage closure (LAAC) procedures offers a compelling solution for patients with AF, simultaneously addressing symptom control and stroke prevention in a single procedure. The recent creation of a new Medicare Severity Diagnosis Related Group (MS-DRG) by Centers for Medicare and Medicaid Services (CMS) for this combined procedure has improved the reimbursement structure, making it more economically viable for hospitals to perform. This CV business white paper compiles best practices from seven experienced centers across the country, offering valuable insights into developing a successful concomitant AF ablation and LAAC program. By leveraging the expertise of these established programs, new centers can optimize their approach to this innovative and increasingly important treatment modality for patients with AF.

CONCOMITANT PROCEDURES

provide a streamlined approach that:

- **BENEFITS** patients
- **INCREASES** operational efficiency
- **REDUCES** resource burden

SUMMARY

- Concomitant therapy provides a patient-centric model of care that streamlines delivery while prioritizing patient safety and improving patient experience by reducing hospital visits and anesthesia exposure.
- Operators experienced in performing concomitant AF ablation and LAAC procedures have achieved positive outcomes, including safety, with selection of appropriate patients, careful procedural planning and post-procedural care.
- Effective transeptal puncture (TSP) strategies, supported by advanced tools like the VersaCross Connect™ and the WATCHMAN TruSteer™ Access System, along with intraprocedural imaging, are key elements to ensure successful performance of concomitant procedures. Proceduralist competency with standalone AF ablation and LAAC procedures is essential prior to adopting a concomitant approach.
- Guidelines and indications drive patient selection. Patient-centric clinical decision-making for concomitant procedures may particularly benefit patients for whom limiting anesthesia exposure is particularly impactful, such as the elderly or those with multiple co-morbid conditions.
- Many sites leverage advanced practice providers (APPs) for structured follow-up visits, ensuring continuity of care and efficient monitoring of patient progress. This approach supports early detection of complications and allows timely adjustments to treatment plans, demonstrating the value of specialized, consistent care throughout the recovery period.
- Much like when procedures are performed independently, the use of same-day discharge protocols in concomitant procedures when appropriate, combined with follow-up calls has helped streamline patient care while maintaining safety during post-procedural recovery.*

**CMS designates percutaneous LAAC procedures as Inpatient Only (IPO) procedures. These procedures are therefore only reimbursed by Medicare and Medicare Advantage plans when performed in an inpatient site of service. Concomitant LAAC and AF ablation procedures are subject to the same CMS site of service requirements since they are performed during the same operative session.*

INTRODUCTION: THE RATIONALE FOR CONCOMITANT PROCEDURE ADOPTION

Driven by several key factors, the adoption of concomitant AF ablation and LAAC procedures has gained traction across multiple cardiac programs. Institutions that have prioritized this patient-centric approach recognize the clear benefit of reducing the need for multiple hospital visits, minimizing patient exposure to anesthesia, and streamlining care delivery.

MedAxiom conducted a comprehensive analysis to gather expert insights on the adoption of concomitant procedures. This investigation included a roundtable discussion and interviews with seven leading cardiovascular sites. The expert opinions presented in this paper reflect in-depth information on patient selection criteria, procedure preparation protocols, peri- and post-procedural care strategies, and follow-up processes **(Table 1)**. These findings represent the collective wisdom of experienced practitioners in the field of cardiovascular medicine.

ADVANTAGES OF CONCOMITANT PROCEDURES

- Provide symptom relief and stroke prevention in one procedure instead of two.
- Potential reduction in the total exposure time to oral anticoagulation.
- Address risks of changes in contractillity and thrombus formation that arise with potential LAA electrical isolation.
- Reduce resource duplication through a single procedural encounter.

Table 1: Participating Site Demographics

Site	Facility Type	Number of Beds	Number of Labs	Number of EPs Performing Concomitant Procedures	Years Performing Concomitant Procedures
AnMed	Community	495	2	1	3 years
Cleveland Clinic	Academic	1,290	9 (and adding a 10th)	8	8 years
NYU Langone Health	Academic	591	6	2	2 years
Scripps Memorial	Teaching Hospital	405	5 (with 6th opening soon)	2+	More than 5 years
St. David's HealthCare	Teaching Hospital	371	6	4	More than 5 years
St. Luke's Mid America Heart Institute	Teaching Hospital	508	3	2	4 years
Vanderbilt Health	Academic	1,741 across its facilities	4	3	More than 5 years

EPs = electrophysiologists

Early adoption and research involvement played vital roles in facilitating the approval and integration of concomitant procedures in programs. Many centers participated in clinical trials like OPTION, allowing them to demonstrate the benefits associated with combining the procedures.[1]

While patient care remains the primary focus, economic considerations also factor into adoption decisions. The introduction of the new MS-DRG 317 by CMS for concomitant AF ablation and LAAC procedures marks a significant development in cardiovascular care reimbursement. This change reflects the recognition that combining these procedures requires specific resources and clinical expertise.

All organizations work closely with their revenue cycle/business analyst teams to understand the reimbursement implications of supporting and growing concomitant procedures. The actuality of those economic implications varied based on the individual market and payor landscape. With the recent addition of specific reimbursement for concomitant procedures, collaborating with commercial payors to implement these codes into contracts and negotiate favorable rates is the next step. This includes sharing societal guidelines and closely monitoring the economic impact for all parties.

Economic considerations for concomitant procedures should include an analysis of:

- Payor mix.
- Negotiated rates.
- Patient demographics.
- Procedure volume.
- Resource utilization.
- Complication rates.
- Market competition.

MS-DRG 317 for combining AF ablation and LAAC in one lab episode offers hospitals an **ECONOMICALLY VIABLE PATHWAY** to perform these procedures.

BEST PRACTICES FOR PATIENT SELECTION, PROCEDURE PREPARATION AND PROCESS PLANNING

The successful implementation of concomitant AF ablation and LAAC procedures requires careful patient selection, thorough preparation and efficient planning processes, all of which are similar to the requirements for standalone procedures. Based on the experiences of multiple cardiac programs, several key processes have emerged to optimize these procedures.

Patient Selection and Evaluation

Patient selection for concomitant procedures involves a similar assessment during initial consultations as in standalone procedures. Several sites report seeing an increase in patients requesting a referral for evaluation due to increased awareness of the availability of concomitant procedures. Electrophysiologists reported being more cognizant of determining patient eligibility for LAAC when completing consults for AF ablation since they began performing concomitant procedures. Many institutions use scoring systems to determine current eligibility and facilitate patient discussions. For instance, one organization has integrated HAS-BLED and CHA_2DS_2-VASc calculators into their electronic health record (EHR) to facilitate eligibility decisions. Another employs the SPARCtool to aid in required shared decision-making discussions about LAAC with patients.

In patients that qualify for AF ablation and LAAC to be performed individually, populations that may especially benefit from concomitant procedures include:

- Patients with bleeding concerns.
- Patients who need to avoid long-term anticoagulation.
- Younger patients facing long-term anticoagulation risks.
- Older patients requiring extensive ablation.
- Older patients who should avoid multiple exposures to general anesthesia.
- De novo paroxysmal AF patients and re-do AF ablation patients.
- Patients traveling far distances.
- Patients requesting the procedure.

Planning Processes

The planning process for concomitant procedures often involves dedicated teams managing prior authorization and documentation. An academic center reported an estimated 30-day approval process but proactively schedules procedures while awaiting approval. For one of the participating sites, the key is using templated notes and shared decision-making phrases in their EHR to assist in gaining approval.

Patient education is a critical component of the planning process. Many institutions allocate time during office visits for individual education about AF ablation and LAAC procedures. For example, one site sends educational materials via email one week before the procedure to ensure patients are well-informed.

Several programs employ a team-based approach with collaboration between EPs and APPs. Most institutions have dedicated coordinators overseeing the entire process to ensure effective team collaboration and streamlined scheduling. The use of specialized software such as Hawkeye™ helps to streamline patient coordination and improve operational efficiencies for the LAAC component of concomitant procedures.

Procedure Preparation

Effective preparation for concomitant procedures involves coordinating multiple teams and resources. Three of the institutions allocate longer time blocks for these procedures, typically three hours compared to two hours for each standalone procedure. This extended time allows for the performance of both AF ablation and LAAC. However, there is a net gain in total procedural lab time by combining procedures and not turning the room over twice, etc.

Imaging strategies vary when planning concomitant procedures based on physician preference and experience with standalone procedure. Some physicians obtain a TEE or computed tomography (CT) in advance of the procedural day while others rely on TEE on the day of the procedure for WATCHMAN™ device sizing. One program has streamlined their pre-procedure imaging workflow by integrating imaging orders that automatically trigger TEE scheduling for concomitant procedures.

Combining procedures **RESULTS IN OVERALL LAB TIME SAVINGS.**

KEY LEARNINGS

Having one team to coordinate both procedures is important as team members understand the needs of the patients, physicians and lab staff. By verifying the prior authorization for both ablation and LAAC before the procedure day, adjustments can be made to the EP lab schedule and the financial risk of performing unapproved procedures can be reduced.

Best Practices Summary

- ✓ Utilize scoring systems (e.g., CHA_2DS_2-VASc, HAS-BLED, SPARCtool) for patient selection and documentation.
- ✓ Employ dedicated team members for prior authorization, coordination and advanced practice support.
- ✓ Implement standardized education materials for patient preparation.
- ✓ Integrate specialized software such as Hawkeye™ to streamline patient coordination & optimize operational efficiencies for the LAAC component.
- ✓ Allocate extended time blocks for concomitant procedures.
- ✓ Use flexible imaging approaches based on physician preference.
- ✓ Develop a patient education strategy for concomitant procedures.
- ✓ Foster collaboration between EPs and APPs.

By adhering to best practices, the seven participating sites have been able to

OPTIMIZE THEIR CONCOMITANT PROCEDURE WORKFLOWS, ENHANCE PATIENT CARE AND IMPROVE OPERATIONAL EFFICIENCY.

BEST PRACTICES FOR PERI-PROCEDURAL CARE PROCESSES

Combining AF ablation with LAAC into a single procedure comes with several intraprocedural care considerations. The combination of site testimonies and the physician expert roundtable produced key insights into intraprocedural care considerations, including transeptal puncture (TSP) strategy, device sizing and intraprocedural imaging.

Transeptal Puncture Strategy

Both procedures require crossing the intra-atrial septum, acknowledging specific anatomic considerations and a TSP strategy to facilitate effective access to the left atrium and left atrial appendage. All physicians noted the importance of good intraprocedural imaging to guide TSP placement and are strategic with placement of the ablation TSP to ensure the best approach for the LAAC portion. Most noted they could complete both procedures with a single TSP using a TSP approach, often similar to what they would use for LAAC. Additional variables that need to be considered when developing an effective TSP strategy are the use of intracardiac echocardiography (ICE) and the extent of mapping required. Several programs have found the use of the TruSteer access system simplifies their TSP decision by extending the range of catheter access during the LAAC procedure.

AF Ablation

Interviewed physicians primarily used pulsed field ablation (PFA) for the AF ablation portion of the procedure, performing it before completing the LAAC. PFA's typically shorter procedure duration and targeted ablation safety profile have increased physicians' comfort in combining procedures without introducing increased risk to patients.

Device Sizing

All physician roundtable participants were asked about device sizing considerations when performing a WATCHMAN FLX™ Pro LAAC Device implantation immediately following an AF ablation procedure. There was some reported variation in insights/experience related to the type of AF ablation technology. Watchman FLX Pro has an overlapping sizing matrix, meaning that for a given appendage, two devices could reasonably be chosen while staying within the 10 to 30% allowable compression range. Several physicians noted that they tended to choose the larger of the two device sizes in concomitant procedures due to the possibility of post-AF ablation edema. As an added precaution, select sites chose to leverage pre-procedural imaging to compare pre-/post-ablation appendage morphology much like they would when performing lone Watchman implantation.

Intraprocedural Imaging

Some physician operators proficient with the gold standard use of TEE for LAAC have adopted ICE for imaging guidance, though most respondents use ICE in combination with TEE during concomitant procedures. The use of 2D versus 3D ICE was variable, but all noted its value for both AF ablation and LAAC procedures. Of note, the use of cardiac anesthesiologists for intra-procedural TEE was a mechanism for providing flexibility with scheduling imaging providers.

BEST PRACTICES FOR POST-PROCEDURAL CARE PROCESSES

Post-procedural monitoring for concomitant procedures aligns with standard practices for standalone AF ablation and LAAC, focusing on hemodynamic and electrical stability, vascular site hemostasis and discharge preparation. Patients typically recover in a post-anesthesia care unit (PACU) for the first hour before transitioning to an inpatient unit or post-procedure area. Some facilities reduce transfers by using dedicated phase one recovery beds with specialized staff.

Standardized order sets guide post-procedure care, including access site closure and bedrest duration, with figure-of-eight sutures and closure devices being common for hemostasis. To further support patient comfort, patients are allowed to ambulate after two to four hours if stable during the recovery period.

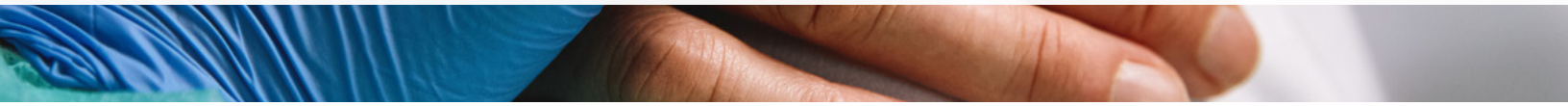
Same-day discharge practices vary with some physicians favoring overnight stays due to patients' ages, comorbidities or travel distances. Discharge instructions must address both procedures, highlighting medication changes and follow-up care. Scheduled follow-ups and testing are standard to ensure timely post-procedure evaluations.

Post-procedural monitoring for concomitant procedures

ALIGNS WITH STANDARD PRACTICES

for standalone AF ablation and LAAC.

Download a sample Concomitant Procedure Note



BEST PRACTICES FOR PATIENT FOLLOW-UP PROCESSES

Many institutions leverage APPs for early follow-up appointments two to four weeks post procedure.

Well-defined imaging protocols emphasize regular assessment using TEE or CT scans.

Interdepartmental collaboration helps ensure patient adherence to follow-up imaging.

Anticoagulation management follows physician preference based on standalone procedures and varies according to patient needs.

Patient education, a cornerstone of anticoagulation management, is essential for patient adherence and optimal outcomes. Teams must ensure patients fully understand the timeline for potential changes and the reasons behind them. Post-procedure care practices also demonstrate thoughtful adaptations across the sites. For example, nurses at two of the sites proactively follow-up with patients the next business day to check on wound healing, medication adherence and overall recovery. This approach underscores the importance of post-discharge follow-up as a safety net to ensure quality outcomes. Similarly, another site offers a unique provision: patients with recurrent AF after the initial TEE can undergo cardioversion without repeating the TEE when LAAC has been performed concomitantly, simplifying care for these specific cases. These practices reflect a commitment to balancing efficiency with patient-centered care. Across the sites, the consistent involvement of APPs emerges as a best practice. Their role provides personalized care and maintains the quality and continuity of follow-up processes. Despite the variety in specific practices, common themes include a heavy emphasis on structured follow-up, early detection of complications through imaging, strategic anticoagulation management and proactive patient education. Collectively, these strategies are designed to optimize patient outcomes, minimize risks, and ensure long-term success for patients undergoing these complex procedures.

Team-based care strategies are
DESIGNED TO ENSURE LONG-TERM SUCCESS
for patients undergoing these complex procedures.

CONCLUSION

The adoption of concomitant AF ablation and LAAC procedures marks a significant advancement in cardiovascular care. Seven participating sites found that combining these procedures benefits patients, increases operational efficiency, and reduces healthcare costs. Insights from multiple sites and expert physicians emphasize the advantages of a concomitant approach for patients needing both AF ablation and LAAC and reduces the risk of multiple anesthesia episodes. The OPTION concomitant arm showed a 44% reduction in International Society on Thrombosis and Haemostasis non-procedural bleeding with equivalent stroke protection versus oral anticoagulants at 36 months. Programs noted the importance of patient selection, careful procedural planning and comprehensive post-procedural care. As concomitant procedures evolve, ongoing research, collaboration and adherence to best practices will further refine implementation and optimize patient outcomes.

Concomitant procedures **ALLOW FOR A SINGLE ANESTHESIA EPISODE** for patients.

REFERENCES

1. Wazni OM, Saliba WI, Nair DG, et al., for the OPTION Trial Investigators. Left atrial appendage closure after ablation for atrial fibrillation. *N Engl J Med*. 2024 Nov 16 [E-pub ahead of print]; http://dx.doi.org/10.1056/NEJMoa2408308.

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