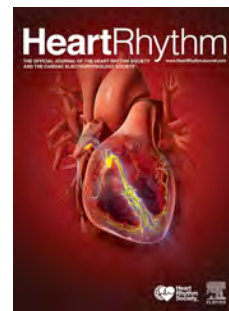


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Combined Epicardial and Endocardial Ablation for Atrial Fibrillation: Best Practices and Guide to Hybrid Convergent Procedures

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2 **Best Practices and Guide to Hybrid Convergent Procedures**

3
4 **Short title:** Hybrid convergent procedure best practices

5
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53 **Abstract**

54 The absence of strategies to consistently and effectively address non-paroxysmal atrial fibrillation (AF)
55 by nonpharmacologic interventions has represented a longstanding treatment gap. A combined
56 epicardial/endocardial ablation strategy, the hybrid Convergent procedure, was developed in response
57 to this clinical need. A subxiphoid incision is used to access the pericardial space facilitating an epicardial
58 ablation directed at isolation of the posterior wall of the left atrium. This is followed by an endocardial
59 ablation to complete isolation of the pulmonary veins and for additional ablation as needed. Experience
60 gained with the hybrid Convergent procedure during the last decade has led to the development and
61 adoption of strategies to optimize the technique and mitigate risks. Additionally, a surgical and
62 electrophysiology “team” approach including comprehensive training is believed critical to successfully
63 develop the hybrid Convergent program. A recently completed randomized clinical trial indicated that
64 this ablation strategy is superior to an endocardial only approach for patients with persistent AF. In this
65 review, we propose and describe best practice guidelines for hybrid Convergent ablation based on a
66 combination of published data, author consensus, and expert opinion. A summary of clinical outcomes,
67 emerging evidence, and future perspectives are also discussed.

68

69 **Keywords:** atrial fibrillation; hybrid Convergent ablation; epicardial ablation; endocardial ablation;
70 persistent atrial fibrillation; pulmonary vein isolation; posterior wall isolation

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77 Introduction

78 Atrial fibrillation (AF) is common and can lead to significant morbidity and impaired quality of
79 life (QOL).¹ Treatment strategies include risk factor modification, prevention of thromboembolic events,
80 medical management with rate and rhythm control drugs, and percutaneous endocardial catheter and
81 surgical ablation.¹ Success of these strategies is variable and influenced in part by AF type and duration,
82 extent of electrical and structural atrial remodeling, and mechanisms and patterns of arrhythmogenic
83 sources. Rhythm control efforts by catheter ablation have a high success rate for paroxysmal AF,^{2, 3}
84 however less so for persistent AF.^{4, 5} The potential for open-heart surgical ablation to treat non-
85 paroxysmal AF is well described,⁶ but typically performed as a component of another cardiac surgical
86 procedure. However, most patients with persistent AF do not require open-heart surgery and
87 historically have had more limited AF management options.

88 This treatment gap prompted the development of a minimally invasive, epicardial and
89 endocardial ablation (“Convergent”) procedure focused on patients with non-paroxysmal AF, combining
90 advantages of both techniques.⁷ During the last decade, this “hybrid” approach has garnered increasing
91 acceptance in clinical practice, with several reports of promising antiarrhythmic outcomes in challenging
92 disease states, as well as modifications to maximize safety and clinical outcomes.⁷ One key aspect of this
93 treatment strategy is that it harmonizes epicardial and endocardial ablation components to effectively
94 target key drivers of AF, including the pulmonary veins (PVs) and the left atrial posterior wall (LAPW).
95 The LAPW (or “PV myocardium”) shares similar embryologic origins and electrophysiologic properties
96 with the PVs,⁸ is predisposed to develop fibrosis,⁹ and thus recognized as an important source of AF.
97 However, its isolation with standard endocardial catheter ablation alone is associated with suboptimal
98 durability and significant risk of proarrhythmic atrial flutters,^{10, 11} non-transmural lesion creation,¹²
99 suboptimal long-term efficacy,¹³ and risks associated with outward delivery of radiofrequency (RF)
100 energy including thermal injury.

101 The recently completed CONVERGE randomized clinical trial¹⁴ demonstrated a substantially
102 advantageous AF outcome following hybrid ablation versus endocardial-only ablation in nonparoxysmal
103 AF, which we believe will fuel greater interest in this combined treatment strategy. Based on the
104 authors' substantial combined experience, herein we describe key technical and programmatic
105 components of the procedure distinct from traditional ablative strategies and best practices critical for
106 implementation of a successful combined surgical and electrophysiological AF program. Lastly, we
107 discuss emerging evidence and future perspectives of this hybrid approach.

108 **Hybrid Convergent procedure overview**

109 The hybrid Convergent procedure is a minimally invasive, closed-chest procedure performed on
110 the beating heart that combines epicardial RF ablation—focused on the LAPW—followed by
111 complementary endocardial catheter ablation. The epicardial component seeks to debulk as much of the
112 LAPW as can be accessed, principally limited by the oblique sinus. Posterior segments of the PV
113 ostia/antra may also be reached and ablated in most cases. The endocardial component supplements
114 the epicardial lesions around the pericardial reflections and any incompletely ablated LAPW areas, and
115 addresses any remaining gaps between the PV and LAPW lesion sets (including anterior segments),
116 ensuring PV electrical isolation. The endocardial component can also include a cavo-tricuspid flutter line
117 and addresses any other substrate believed to be contributory to the clinical presentation.

118 In the hybrid Convergent procedure, a closed-irrigation, unipolar RF catheter device (Epi-Sense
119 Guided Coagulation System, AtriCure, Inc., Mason, OH) is used for epicardial ablation under endoscopic
120 visualization. The device is inserted through a pericardioscopic cannula (SUBTLE, AtriCure, Inc.) to reach
121 the LAPW and maneuvered in the pericardial space using the cannula and endoscope (Figure 1). During
122 ablation, epicardial tissue is suctioned by vacuum onto the RF coil on one side of the device, stabilizing
123 the device on the atrium and optimizing energy delivery. Saline perfusion within the device maintains

124 tissue hydration and provides insulation and cooling. The RF energy delivery achieves coagulation as the
125 temperature approaches 60°C, but does not reach excessive temperatures such that tissue vaporization
126 occurs. Each lesion is created by a 90-second application of alternating current via an impedance-based
127 power control algorithm. Lesions are overlapped across the entire LAPW to promote contiguity and
128 transmural, and thus minimize gaps with the intention of creating a homogeneous region of electrical
129 silence. Endocardial catheter ablation is then performed through a standard femoral approach. Figure 2
130 illustrates the spectrum of hybrid Convergent approach lesion sets.

131 **Practical planning for hybrid Convergent procedures**

132 *Multidisciplinary Convergent “team.”* Hybrid Convergent ablation combines expertise from
133 cardiothoracic surgery and electrophysiology. Coordination and collaboration among the
134 multidisciplinary team members are paramount to a successful program. Each institution may have an
135 individualized setup, but detailed planning is required and may involve changes to existing workflows.
136 Ideally, a designated navigator acts as the liaison between the patient and hospital staff, coordinates
137 patient education and staff training, and facilitates stakeholder discussions. Staff training on pre- and
138 post-operative care should also occur well in advance of the first case to allow for adjustments and
139 changes to the standard protocols. Peri-operative coordination is crucial as it may involve modification
140 of medical therapies, and mitigation of post-operative complications as compared to catheter-only
141 ablation. Post-operative recovery may occur in the surgical ward, ICU, or cardiac care unit depending on
142 institution; resource availability should be considered beforehand. Interdepartmental education of
143 nursing staff and advance practice providers are other important considerations.

144 *Single Length of Stay (LOS) versus Dual LOS (or staged) programs.* One major decision is whether
145 the epicardial and endocardial portions will be performed within one or two hospital admissions. Within
146 Single LOS, epicardial and endocardial procedures can occur back-to-back in the same or separate suites,

147 or over sequential days. If using a single suite, the lab arrangement will need to be organized and
148 planned in advance to accommodate staff, primary operator, associated equipment/devices and
149 imaging systems for both procedures (Figure 3). For Dual LOS, the epicardial component typically occurs
150 in the cardiac OR and the endocardial component is scheduled, depending on institution, approximately
151 31 to 90 days later in the electrophysiology lab (Figure 4).

152 Respective outcomes from single and dual LOS have not been formally compared. We believe
153 the key ablation undertaking is epicardial and complete LAPW isolation. Thus, the epicardial portion is
154 the initial component of all hybrid approaches (prior to systemic anticoagulation during the endocardial
155 phase). The endocardial component, whether performed early or later, complements the epicardial
156 component by touching up the LAPW lesion set if needed based on an electro-anatomic map; and by
157 performing additional ablation as needed based on individual patient procedure and clinical
158 characteristics, such as PV isolation in a first-time patient. Institutional logistics, reimbursement
159 patterns, and physician and patient preferences and needs will largely influence the optimal local
160 procedure scenario. Especially at the outset, we recommend surgeons and electrophysiologists attend at
161 least part of the other procedure to understand each other's contribution. Feedback from the
162 electrophysiologist on the LAPW lesion set may be particularly helpful during the surgical learning
163 phase.

164 **Patient selection**

165 *Patient eligibility.* Prior to implementation, patient selection criteria should be thoughtfully
166 considered and agreed upon by the team. In general, patients should have symptomatic, drug-
167 refractory, persistent or long-standing persistent AF. Initial hybrid convergent procedure for paroxysmal
168 AF is not recommended given the good success rate of endocardial PVI. A program could consider

169 patients who have failed previous catheter ablation; some centers focus on patients considered to be
170 PVI non-responders to facilitate non-PV ablation of the LAPW.

171 Hybrid Convergent ablation was applied as a *de novo* procedure in the CONVERGE clinical trial,¹⁴
172 and for patients with enlarged atria (>4-5 cm), high BMI, and longer duration of longstanding persistent
173 AF. Given that catheter ablation improves outcomes in heart failure patients with persistent AF,¹⁵
174 patients with heart failure and reduced ejection fraction could potentially be considered; some reports
175 have included low ejection fraction subgroups.^{16, 17}

176 *Contraindications and restrictions.* We consider contraindications to hybrid Convergent ablation
177 to include thrombus in the left atrial appendage, previous sternotomy/heart surgery, unstable coronary
178 artery disease, stroke or myocardial infarction within 3 months, history of significant Barrett's
179 esophagitis, active infection or sepsis, and pregnancy (Figure 5). Those requiring structural cardiac
180 surgery are rather considered as candidates for concomitant surgical ablation, however physicians may
181 consider patients with mild to moderate valvular disease for hybrid Convergent. We recommend
182 applying more stringent selection criteria for the initial patients when a hybrid Convergent program is
183 launched, or with a new team. After experience on these "optimal" patients, relative restriction criteria
184 and future patient eligibility can be re-assessed and adjusted.

185 *Preadmission testing.* After initial selection, preadmission testing should be performed for
186 additional screening (Figure 6). Exact testing should be agreed upon by the cardiothoracic surgeon and
187 electrophysiologist, but commonly includes a CT or MRI to evaluate anatomy and PV stenosis (if prior
188 ablation), transthoracic (TTE) or transesophageal echocardiogram (TEE) to evaluate mitral regurgitation,
189 thrombus in the left atrium (LA) and LAA, LA size, and left ventricular ejection fraction (LVEF). Baseline
190 EKG and ambulatory ECG monitoring are typically performed. Basic pre-operative laboratory tests and
191 anticoagulation status should be evaluated. An ischemia workup can be considered in select patients.

192 Peri- and post-operative medication strategies and follow-up

193 Specific aspects of peri- and post-operative medication strategies will vary institutionally and for
194 single versus dual LOS. A comprehensive anticoagulation protocol including preoperative, intra-
195 operative and post-operative anti-coagulation management should be formally planned to prevent
196 potential thromboembolic events. While we describe our basic approach to medical therapy below, in
197 Figure 6 and Supplement, each institutional team must have a plan in place for anticoagulation, anti-
198 inflammatory medication, and pain management.

199 *Peri-operative anticoagulation strategy.* Consensus on the specific peri-operative
200 anticoagulation regimen does not exist, however there is consensus supported by evidence, that time
201 off of anticoagulation should be minimized. Patients should remain on oral anticoagulation in the weeks
202 prior to the procedure to avoid thrombus formation. Often, direct oral anticoagulants (DOACs) are
203 suspended 24 to 48 hours (depending on dosage and renal function) prior to the procedure. For patients
204 on warfarin, INR levels should remain within a therapeutic range, and should undergo bridging with low
205 molecular weight heparin when the INR falls below 2.0 after warfarin discontinuation. As with
206 conventional catheter ablation, the patient should be fully heparinized to the electrophysiology lab
207 standard during endocardial instrumentation of the LA.

208 *Post-operative medication regimen.* Anticoagulation can usually be resumed the evening of the
209 procedure unless otherwise indicated by risk or complexity of the case, or early or excessive
210 postoperative bleeding. Post-operative pain and pericarditis can be managed through several strategies
211 described in Figure 6 and Supplement depending on co-existing morbidities. Long-term anticoagulation
212 following the procedure should be as indicated by AF and ablation guidelines, and should not be
213 discontinued in the two months following the procedure.

214 *Clinical follow-up.* Specific follow-up and rhythm monitoring will vary institutionally. Surgical
215 follow-up usually occurs 1-4 weeks after the single LOS or epicardial procedure and with
216 electrophysiology 1-3 months after the single LOS or endocardial procedure. A crucial follow-up step
217 specific to hybrid Convergent procedures is consideration of a TTE performed approximately 2-4 weeks
218 following the procedure (unless indicated earlier by symptoms) in most or all patients to screen for
219 inflammatory-mediated pericardial effusions and Dressler's syndrome (Figure 6).

220 **Cardiothoracic surgery team: key components of the hybrid Convergent procedure**

221 Detailed surgical considerations and operative technique have been reported.¹⁸ We describe
222 here general factors relevant to the surgical portion of the hybrid Convergent procedure. Device
223 instructions for use should be followed for patient preparation, device setup, and pericardial access.
224 Anatomical landmarks and the LAPW are shown in Figure 7.

225 *Epicardial ablation.* Prior to ablation, the relative position of the ablation device should be
226 assessed, utilizing the black arrows and dots to orient the electrodes toward the epicardium and away
227 from the posterior pericardium (Figure 1). The cannula can be retracted slightly after device positioning.
228 The vacuum is then engaged to draw epicardial tissue into the device before ablation; it should not be
229 active when moving the device. The pericardial space is irrigated through the cannula to limit
230 temperature rises; baseline temperature should be noted and continuously monitored. The TEE (and
231 NG/OG tube if applicable) should be removed or retracted during ablation to avoid interference with
232 temperature monitoring. Each ablation is applied for 90 seconds and an impedance drop of at least 10%
233 (on the RF generator) should be observed during the first 20 seconds, indicating adequate contact
234 between the catheter and heart.

235 *Lesion sets.* At minimum, the epicardial ablation should include parallel, connecting lesions
236 across the LAPW extending from the left and right pericardial reflections at the PV/LA junction. The total

237 number of ablations (typically 20-30) depends on the patient and atrial size. The extent of the superior
238 ablation row will be dictated by the pericardial reflection along the transverse sinus: the Epi-Sense
239 catheter should be advanced as cephalad as possible until resistance is met, which indicates contact
240 with the pericardial reflection. Often while placing the first row of ablation lines the catheter will catch
241 on the spine and deflect the catheter and cannula. It is important to mentally visualize these effects on
242 ablation and avoid gaps. It is not uncommon to see preserved myocardial voltage in the shape of “V” at
243 the roof of the endocardial map as a result of the transverse pericardial reflections or protrusion of the
244 vertebral column preventing an appropriate purchase of the myocardium by the catheter. To that end,
245 the lesion set should be systematic (as viewed from the surgeon’s visual perspective), starting as
246 superior right as possible (vicinity of posterior surface of the left superior PV) and then move to left (to
247 the posterior surface of the right superior PV). Once the first row is completed, the second row is
248 started just below the first lesion and carried over to the left.

249 The inferior border of ablation is the caudal margin of the inferior PVs. The coronary sinus (CS) is
250 easily visualized in the 3 o’clock region or on the left side of the patient’s heart, but is more difficult to
251 visualize as it courses across the posterior LA towards the IVC. Imagining its oblique course is helpful to
252 determine the inferior extent of the lesion set. The surgeon must continually observe the inferior margin
253 of both inferior PVs and the CS in order to avoid ablation of the left atrial isthmus. Inadvertent ablation
254 of this area can predispose the patient to post-operative atypical flutter. A healthy 2-cm margin should
255 be maintained from the CS. As one approaches the inferior aspect of the lesion set there often is
256 significant epicardial fat that may limit the effectiveness of these lesions.

257 Whether or not to place lesions anterior to the left and right PVs should be discussed between
258 the surgeon and electrophysiologist. These advanced lesions may be addressed once the team becomes
259 proficient with LAPW ablation. Most electrophysiologists feel comfortable that the endocardial ablation
260 set will isolate the PVs and that the value and focus of the epicardial ablation is on the LAPW.

261 When encountering suboptimal RF delivery, first troubleshoot the catheter making sure suction
262 is adequate and tissue apposition as well as vacuum are maintained. Repeating the lesion is also an
263 advisable next step. Barring a technical issue, it is important to persist as the resulting map can often
264 be surprisingly good despite suboptimal lesion appearance. The device's sensing feature can also be
265 utilized to confirm electrical quiescence.

266 Tissue fibrosis, epicardial or intramyocardial fat, and esophageal temperature rise can affect
267 ablation quality. In cases of fibrosis or fat, the starting impedance may be high and/or the power
268 delivery will vary throughout the duration of the burn. Epicardial fat can be visually recognized by the
269 surgeon and if power delivery does not exceed 10W for more than a few seconds, the ablation should
270 be aborted and the catheter repositioned, even if only by a few millimeters. Ablations that achieve only
271 moderate power delivery can be repeated in the same position without moving the catheter.
272 Esophageal temperature can rise very rapidly in some cases, and should be constantly monitored and
273 ablation stopped if the temperature increases by 0.5-1.0 degree Celsius. Copious irrigation of the field
274 with room temperature saline and repeating ablation will usually allow for adequate ablation.

275 *Completing the epicardial procedure.* When ablation is complete, a drain is advanced through
276 the cannula under direction visualization into the pericardial space. The drain can be passed through the
277 subxiphoid or lateral incision. The drain should remain in place until its output is less than 50-100 cc
278 during a 24-hour period. The wound is irrigated, and local anesthetic or anti-inflammatory medications
279 can be administered. The wound is then closed in layers.

280 **Electrophysiology team: key considerations for the hybrid Convergent procedure**

281 *Strategic considerations.* It is generally agreed that the goals of the endocardial lesion set are in
282 part to create a gapless connection with the epicardial lesion set and to eliminate electrical activity in
283 the desired region of LA substrate. Prior to endocardial ablation, the extent of epicardial ablation is

284 assessed by performing an endocardial voltage map, preferably in sinus rhythm (SR) or with atrial
285 pacing. The lowest possible voltage gate is recommended to avoid false assumptions of ablated tissue.

286 *Understanding pericardial reflections.* Epicardial ablation is performed in the oblique sinus
287 without dissection of the reflections. The pulmonary venous recess and transverse sinus form the limits
288 of the oblique sinus. The pericardial space differs greatly between patients.¹⁹ The greatest variability is
289 seen at the superior aspect of the pericardial space. The roof of the pericardial space does not
290 correspond with a conventional roof line. Connection of the superior margin of the pericardial reflection
291 with the endocardial “roof” is generally the area most likely to require additive endocardial ablation
292 lesions. Endocardial isolation of the superior PVs is mandatory following epicardial ablation; they are
293 rarely ablated from the epicardial space.

294 *The endocardial lesion set.* Transmural extension of epicardial lesions to the endocardium can be
295 hampered by epicardial fat, device apposition difficulty due to a prominent vertebral column, pericardial
296 adhesions, or an unsuitable approach angle into the pericardium. Thus, the operator may need to
297 extend the lesion sets from the margins of the pericardium to areas directly along the LAPW. An
298 endocardial electro-anatomic map can be done to determine the completeness of epicardial (and then
299 endocardial) ablation lesion sets and determine if, how, and where additional endocardial ablation is
300 needed.

301 Adequacy and safety of LAPW endocardial ablation are beyond the scope of this manuscript.
302 Risk mitigation protocols are strongly recommended to decrease the likelihood of atrio-esophageal
303 fistula, cardiac perforation, and phrenic nerve injury.

304 There are several endocardial ablation endpoints that should be met with the procedure.
305 Demonstration of PV isolation is mandatory. A wide area circumferential ablation lesion set is
306 recommended to adequately bridge the gap connecting the epicardial lesion set (Figure 2). If

307 endocardial mapping reveals that the epicardial lesion set does not reach the superior aspect of the LA's
308 anatomical PW, it may be reasonable to create a "roof line" connecting the superior PVs for sufficient
309 critical mass of ablated tissue. However, proximity of the esophagus, phrenic nerve, and spinal
310 prominence may preclude completion. Any endocardial lesion risking collateral injury should be
311 performed carefully weighing the benefit of the lesion against the risk. The inferior extent of the LAPW
312 lesion set is largely governed by the epicardial ablation, which is intentionally limited to the inferior
313 aspect of the inferior PVs. This is understood to minimize potentiality for iatrogenic arrhythmias.

314 The hybrid Convergent procedure is fundamentally an anatomically-focused treatment strategy.
315 Success of the procedure is reflected in rhythm outcomes after a 2-3 month blanking period and
316 completion of both endocardial and epicardial lesions. It is our group's experience that the inability to
317 develop or maintain SR at the procedure's conclusion should not be viewed as a failure and is not
318 indicative of reduced efficacy. Isoproterenol administration or rhythm challenge exercises may be used
319 to guide additional ablation. If macroreentrant tachycardia is observed, additional linear ablation may be
320 considered. Figure 8 shows ablation map examples.

321 *Understanding tissue thickness and epicardial-endocardial dissociation.* The observation that
322 endocardial and epicardial conduction differs in AF has raised concerns with ablation strategies that do
323 not create transmural lesions. The degree of disparity between the endocardium and epicardium may
324 promote and sustain fibrillatory conduction.²⁰ Accordingly, overlap between the epicardial and
325 endocardial lesion sets is preferred to avoid arrhythmogenic gaps and ensure transmuralty.

326 *Endocardial energy sources.* There are several endocardial ablation approaches targeting the
327 PVs and the left and right atria using different techniques and energy sources: irrigated ablation
328 catheter using RF energy and various balloon-based systems (cryoenergy, laser or RF). Most published
329 data, including the CONVERGE trial, used RF catheter ablation in hybrid Convergent procedures. There

330 are limited but very promising data published using endocardial cryoballoon ablation in hybrid
331 Convergent procedures.^{21, 22} Currently, there are no recommendations for the preferred endocardial
332 energy source in hybrid procedures. However, lesion sets that accomplish large area ablation are
333 preferred over strategic linear lesions as the creation of gaps has the potential of invalidating large areas
334 of substrate mitigation.

335 **Safety considerations**

336 Potential adverse events can be mitigated through vigilance and simple solutions (Figure 6).
337 Thermal injuries to the esophagus can be avoided through careful device orientation, esophageal
338 temperature monitoring, and prophylactic irrigation of the pericardial space. Late pericardial effusions
339 due to Dressler's syndrome and cardiac tamponade can be prevented through pericardial drains,^{23, 24}
340 prophylactic medications (colchicine, steroids and/or NSAIDs),^{18, 25} patient education on symptoms, and
341 TTE surveillance at approximately 2-4 weeks.¹⁸ Complications can arise from both epicardial and
342 endocardial procedures, and experienced investigators have reported a learning curve after which
343 complications decreased using such strategies.^{23, 26}

344 **Clinical outcomes**

345 Single and multi-center studies have reported freedom from AF or any atrial tachyarrhythmia to
346 be 66% to 95% at one year following the hybrid Convergent procedure, with 52% to 81% arrhythmia-
347 free without AADs.⁷ A report of 81% of patients in SR after four years suggests favorable durability but
348 additional long-term data are necessary.²³ These results are especially encouraging since the procedure
349 has been frequently utilized in the most refractory patient populations. Risk mitigation and evolution
350 from the epicardial box lesion set to LAPW homogenization are believed to improve procedural safety
351 and efficacy. The shift from a transabdominal to a subxiphoid approach has eliminated concerns

352 regarding rare abdominal complications²⁶. Prospective patient registries of hybrid Convergent ablation
353 are useful to facilitate outcomes reporting.^{22, 27}

354 **Future directions**

355 The prospective, multi-center, randomized controlled clinical trial, CONVERGE (NCT01984346),
356 demonstrated superiority of the hybrid Convergent approach versus an endocardial-only approach for
357 treating nonparoxysmal AF¹⁴. The hybrid approach achieved one-year freedom of atrial arrhythmias
358 absent new/increased dose of previously failed class I/III antiarrhythmic drugs in 67.7% versus 50.0%
359 using conventional techniques (p = 0.036). Further questions remain given the heterogeneity of
360 endocardial approaches and adoption of additional epicardial procedures. Despite variety in current
361 endocardial ablation sets, there is agreement among users to move towards an agreed upon
362 endocardial lesion set(s). Given the potential contribution of arrhythmogenic impulses emanating from
363 the LAA in persistent AF²⁸ there is increasing interest in LAA electrical isolation. While one can attempt
364 to do this with ablation, concerns exist regarding durability and the prothrombotic risk without
365 mechanical closure.²⁹ The hybrid Convergent approach with transthoracic epicardial placement of an
366 AtriClip offers both mechanical and electrical LAA isolation,³⁰ with favorable results in early
367 experience.^{16, 18, 31} Future studies are needed to evaluate whether addition of LAA exclusion and
368 electrical isolation improves clinical outcomes and the best technical approach. Additional endpoints are
369 worth investigating, such as cost-efficacy, AF burden, formal QOL measurements, stroke, and change in
370 LVEF or symptoms in heart failure patients. Further, hybrid ablation strategy adoption may be sensitive
371 to costs for program start-up and maintenance, but a cost-efficacy analysis found the hybrid Convergent
372 strategy to be superior to catheter ablation due to better rhythm control and fewer repeat
373 procedures.³²

374 **Conclusion**

375 The hybrid Convergent procedure is an emerging technique to address nonparoxysmal AF that can be
376 deployed safely and effectively with careful planning, a coordinated team approach, appropriately
377 selected patients, and a full understanding and implementation of risk mitigation tactics. As adoption
378 and experience with the procedure grows, revisiting and revising the suggested workflows illustrated in
379 this paper will be important for optimizing clinical outcomes.

380

381

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386

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Figure 1. Unipolar radiofrequency device for epicardial ablation. A unipolar radiofrequency device inserted inside a pericardioscopic cannula (with endoscope, not shown) is used to make left atrial posterior wall linear ablations. Arrows and dots orient the radiofrequency coil towards the epicardium.

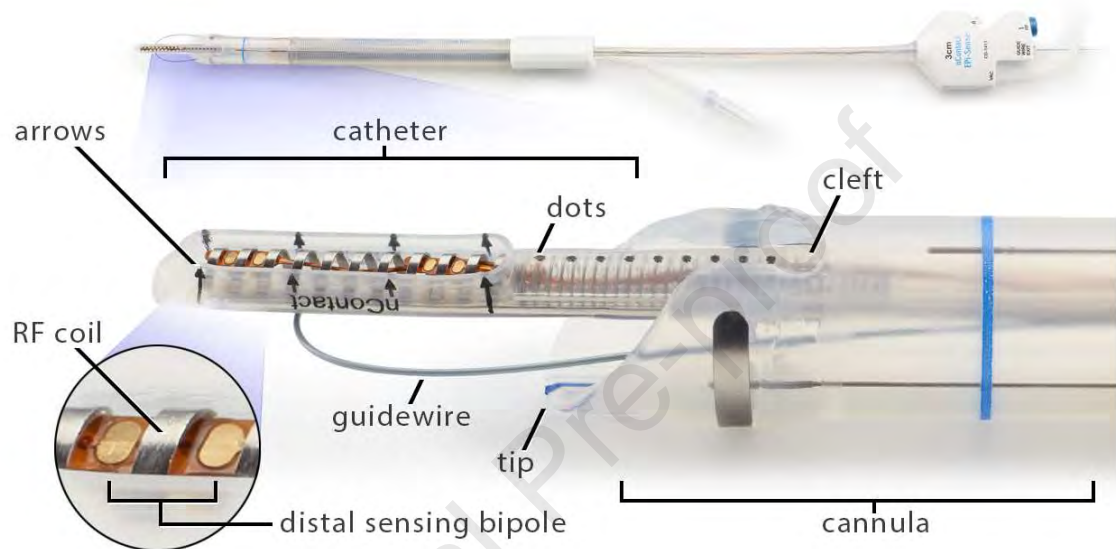


Figure 2. Hybrid Convergent lesion set. Left atrial epicardial/endocardial ablation patterns (left) and lesion set variations (insets). Posterior wall linear lesions are made using the unipolar radiofrequency device. Endocardial ablation is performed to isolate the pulmonary veins (PVs) and address gaps (red circles). Cryoablation PVI is shown in blue. LIPV: left inferior pulmonary vein; LSPV: left superior pulmonary vein; PW: posterior wall; RIPV: right inferior pulmonary vein; RSPV: right superior pulmonary vein; WACA: wide area circumferential ablation

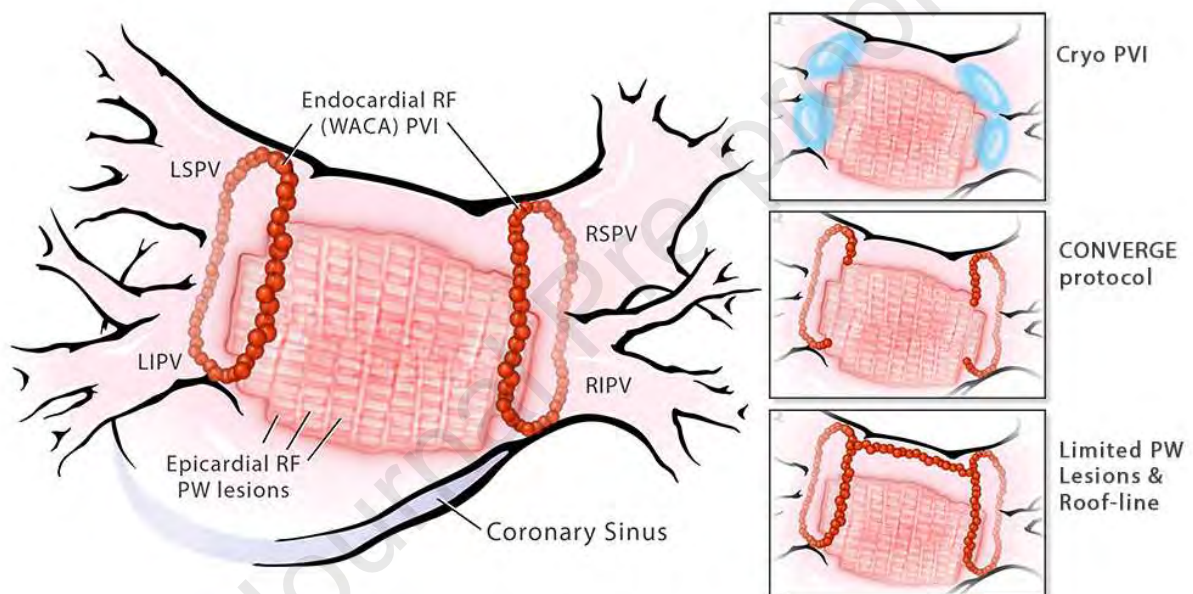


Figure 3. Hybrid operating room (OR)/electrophysiology (EP) laboratory set-up. Example set-up for a hybrid OR/EP lab with key equipment and personnel. Equipment shaded in blue must be within surgeon's view. TEE: transesophageal echo.

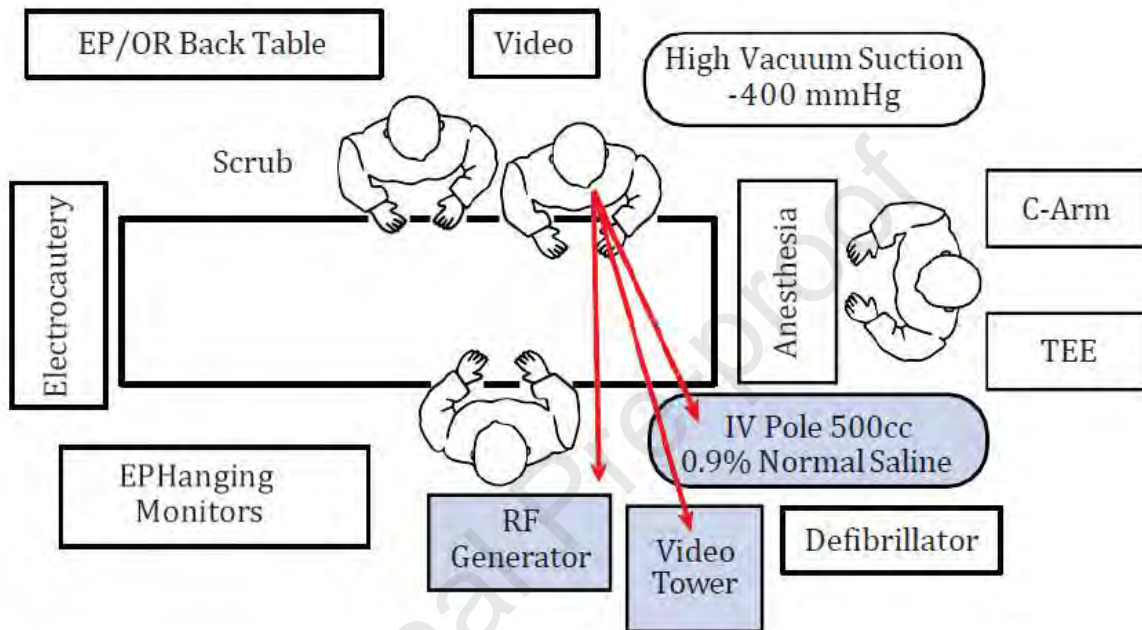


Figure 4. Epicardial and endocardial procedure scheduling. Key considerations of performing the epicardial/endocardial portions in a single hospitalization (1 LOS; same room in one day, separate rooms in one day, or on sequential day) or in two hospitalizations (2 LOS) scheduled 31 to 90 days apart.

1 LOS			2 LOS
Same Day/One Setting: Hybrid Lab (Epi & Endo)	Same Day/Two Settings: Cardiac OR (Epi) & EP Lab (Endo)	Sequential Day: Epi (Day 1) & Endo (Day 2)	Staged Approach: Epi (Day 1) & Endo (31-90 days thereafter)
Pros: Single anesthetic run Immediate feedback on epicardial ablation Cons: Requires availability of Hybrid lab or suitable EP lab Possible increased bleeding risk Longer (single) anesthetic run Possible decreased efficacy of endocardial mapping and ablation due to acute myocardial edema from epicardial ablation	Pros: Single anesthetic run Immediate feedback on epicardial ablation Familiarity of venue for both surgical & EP teams Cons: Transport of intubated patient Coordination of OR/EP lab schedules Longer (single) anesthetic run Possible decreased efficacy of endocardial mapping and ablation due to acute myocardial edema from epicardial ablation	Pros: Convenience of scheduling Familiarity of venue by both surgical & EP teams Rapid feedback on epicardial ablation Likely small reduction in bleeding risk Cons: Potentially longer LOS Two anesthetic runs Questionable increase in procedural risk due to myocardial necrosis if two parts performed > 48 hours apart Potential decreased efficacy of endocardial mapping and ablation due to myocardial edema from epicardial ablation	Pros: Shorter anesthesia run Resolution of acute edema before endocardial procedure Maturation of epicardial lesions Lab and OR productivity Better alignment in scheduling logistics Cons: Patient compliance/interest Two anesthetic runs Lack of immediate feedback on epicardial lesion set

Figure 5. Absolute and relative restrictions for hybrid Convergent procedure. Contraindications (left panel) and relative restrictions by consensus within the Convergent team after acquired experience (right panel). BMI: body mass index; COPD: chronic obstructive pulmonary disease; CVA, cerebrovascular accident; LAA: left atrial appendage; LVEF: left ventricular fraction; MI: myocardial infarction; NYHA: New York Heart Association; TIA: transient ischemic attack.

Patient Selection Criteria	
Contraindications	Relative Restrictions: to be considered with gained experience
<ul style="list-style-type: none"> Current thrombus in LAA Pregnancy History of significant Barrett's esophagitis Active infection or sepsis Previous open heart-surgery Unable to take anticoagulation Unstable coronary artery disease History of MI or stroke in last 90 days Need for concomitant cardiac surgery 	<ul style="list-style-type: none"> NYHA III CKD \geq Stage 3 LVEF $<$ 30% Severe pulmonary hypertension RV outflow tract obstruction History of pericarditis Severe COPD Acute decompensated heart failure History of chest trauma Left atrial size $>$ 7.0 cm^a BMI $>$ 45 Advanced liver disease Connective tissue disorders Existing pericardial adhesions History of thoracic (mediastinal) radiation therapy

^a May have reduced efficacy

Figure 6. Key considerations before, during, and after hybrid Convergent ablation. Key safety risk mitigation strategies are highlighted in white. See Supplement for medication strategy options before, during and after the procedure. AAD: anti-arrhythmic drugs; DOAC: direct oral anticoagulation; ICD: implantable cardioverter device; LAA: left atrial appendage; NSAID: non-steroidal anti-inflammatory drugs; PPM: permanent pacemaker; TEE: transesophageal echocardiogram.

Pre-Admission / Pre-Operative Considerations	Intra- / Peri-Operative Considerations	
<p>Imaging to evaluate mitral valve and identify structural heart valve issues</p> <p>Ischemia workup</p> <p>LV function assessment</p> <p>ICD – Arrange to be turned off for procedure and resumed after</p> <p>PPM – Consider reprogramming based on individual patient</p> <p>TEE on day of procedure to rule out LAA thrombus</p> <p>Anticoagulation – Discontinue DOAC 24-48 hours prior to procedure based on dosing; discontinue warfarin: monitor INR & bridge with low molecular weight heparin</p>	<p>TEE on day of procedure (in OR) to rule out LAA thrombus</p> <p>Esophageal temperature monitoring – probe placed prior to incision with continuous monitoring during ablation; copious saline irrigation of pericardial space</p> <p>Pericardial drain after epicardial ablation</p> <p>Pericardial lavage (for several hours with steroid solution after drain is placed (clamp drain)</p> <p>Anticoagulation – Resume anticoagulation of choice (unfractionated heparin, DOAC) evening of day of surgery if not bleeding; resume home regimen in AM of POD 1.</p> <p>Volume management – Diuresis as needed</p>	<p>Pericarditis management – Options include colchicine, steroids (IV in-hospital, oral at discharge), NSAIDs</p> <p>Rhythm Control – Resume pre-op AADs on evening of day of procedure for at least 60-90 days (blanking period)</p> <p>Post-Operative Considerations</p> <p>Surgical follow-up (1-4 weeks)</p> <p>Transthoracic echocardiogram – Evaluate late pericardial effusion (2-4 weeks)</p> <p>Electrophysiology follow-up (1-3 months)</p>

Figure 7. Ablation of the posterior left atrial wall. Endoscopic view of the posterior left atrial wall and lesions created with the unipolar RF device. Key anatomic features as viewed endoscopically through the cannula are shown. Left and right inferior pulmonary veins (LIPV, RIPV) and left and right superior pulmonary veins (LSPV, RSPV).

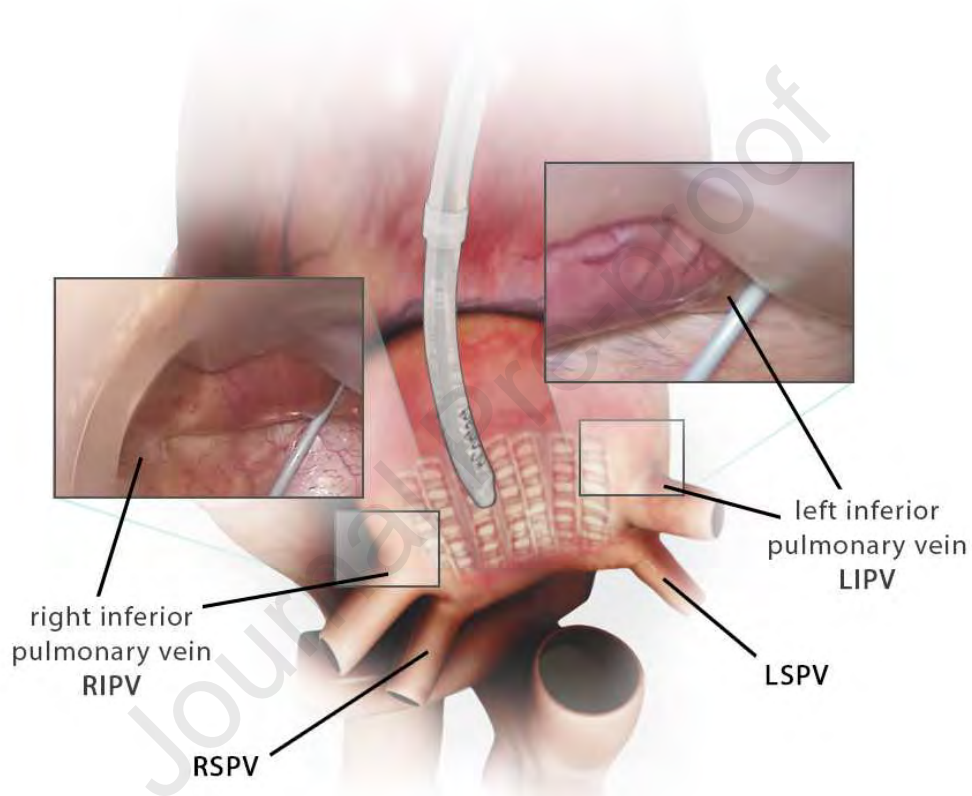
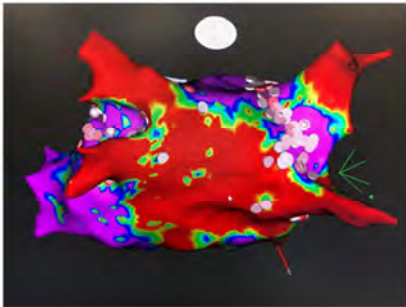
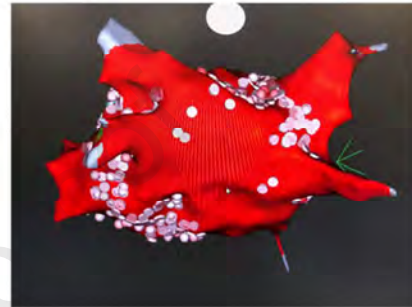


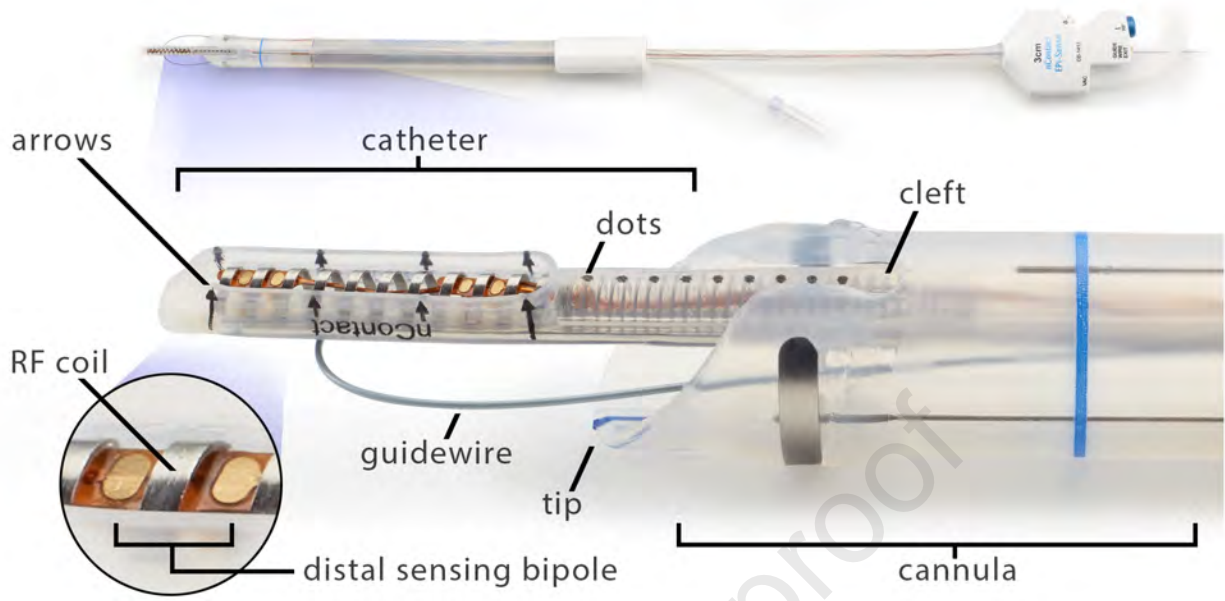
Figure 8. Voltage maps before and after ablation. A. Voltage map post-epicardial/pre-endocardial ablation B. Voltage map following endocardial pulmonary vein isolation (thus completion of hybrid Convergent procedure) with an irrigated radiofrequency catheter.

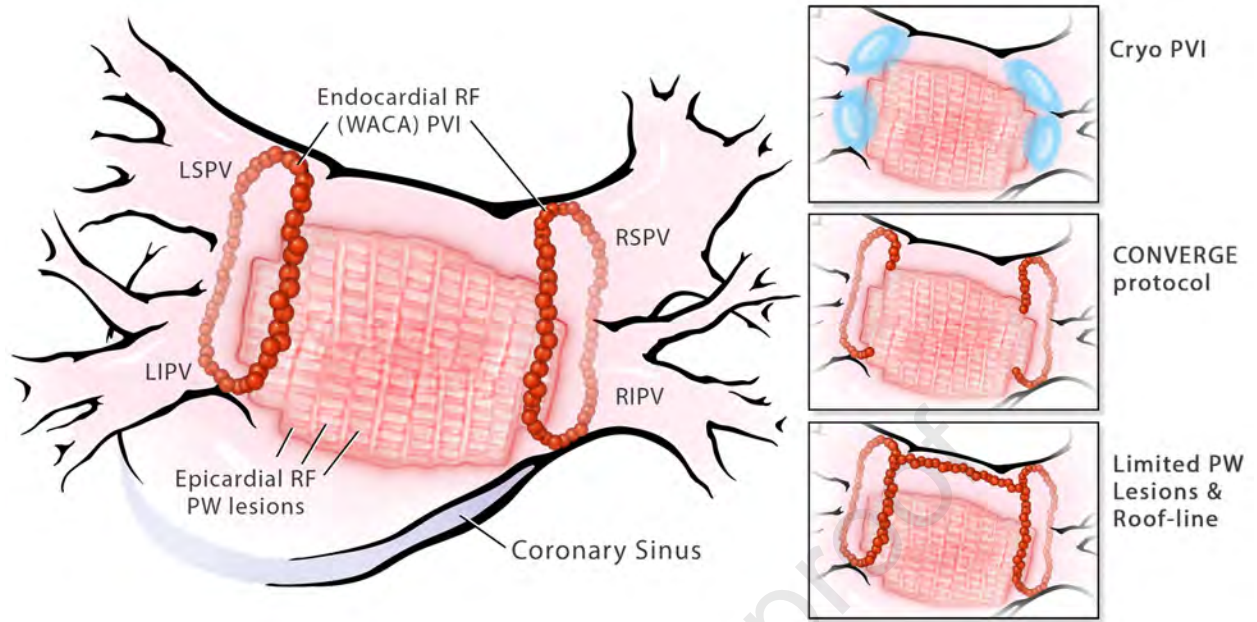
A Post-epicardial/pre-endocardial

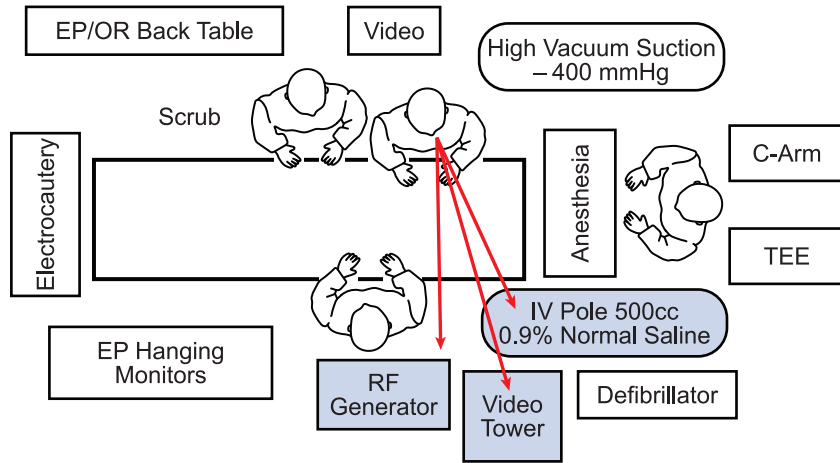


B Post-epicardial/post-endocardial (RF)









Journal Pre-proof

Same Day/One Setting:
Hybrid Lab (Epi & Endo)

Pros:

Single anesthetic run

Immediate feedback on epicardial ablation

Cons:

Requires availability of Hybrid lab or suitable EP lab

Possible increased bleeding risk

Longer (single) anesthetic run

Possible decreased efficacy of endocardial mapping and ablation due to acute myocardial edema from epicardial ablation

Same Day/Two Settings:
Cardiac OR (Epi) & EP Lab (Endo)

Pros:

Single anesthetic run

Immediate feedback on epicardial ablation

Familiarity of venue for both surgical & EP teams

Cons:

Transport of intubated patient

Coordination of OR/EP lab schedules

Longer (single) anesthetic run

Possible decreased efficacy of endocardial mapping and ablation due to acute myocardial edema from epicardial ablation

Sequential Day:
Epi (Day 1) & Endo (Day 2)

Pros:

Convenience of scheduling

Familiarity of venue by both surgical & EP teams

Rapid feedback on epicardial ablation

Likely small reduction in bleeding risk

Cons:

Potentially longer LOS

Two anesthetic runs

Questionable increase in procedural risk due to myocardial necrosis if two parts performed > 48 hours apart

Potential decreased efficacy of endocardial mapping and ablation due to myocardial edema from epicardial ablation

Staged Approach:
Epi (Day 1) &
Endo (31-90 days thereafter)

Pros:

Shorter anesthesia run

Resolution of acute edema before endocardial procedure

Maturation of epicardial lesions

Lab and OR productivity

Better alignment in scheduling logistics

Cons:

Patient compliance/interest

Two anesthetic runs

Lack of immediate feedback on epicardial lesion set

Patient Selection Criteria

Contraindications

Current thrombus in LAA
Pregnancy
History of significant Barrett's esophagitis
Active infection or sepsis
Previous open heart-surgery
Unable to take anticoagulation
Unstable coronary artery disease
History of MI or stroke in last 90 days
Need for concomitant cardiac surgery

Relative Restrictions: to be considered with gained experience

NYHA III
CKD \geq Stage 3
LVEF $<$ 30%
Severe pulmonary hypertension
RV outflow tract obstruction
History of pericarditis
Severe COPD
Acute decompensated heart failure
History of chest trauma

Left atrial size $>$ 7.0 cm^a
BMI $>$ 45
Advanced liver disease
Connective tissue disorders
Existing pericardial adhesions
History of thoracic (mediastinal) radiation therapy

^a May have reduced efficacy

Pre-Admission / Pre-Operative

Considerations

Imaging to evaluate mitral valve and identify structural heart valve issues

Ischemia workup

LV function assessment

ICD – Arrange to be turned off for procedure and resumed after

PPM – Consider reprogramming based on individual patient

TEE on day of procedure to rule out LAA thrombus

Anticoagulation – Discontinue DOAC 24-48 hours prior to procedure based on dosing; discontinue warfarin: monitor INR & bridge with low molecular weight heparin

Intra- / Peri-Operative

Considerations

TEE on day of procedure (in OR) to rule out LAA thrombus

Esophageal temperature monitoring – probe placed prior to incision with continuous monitoring during ablation; copious saline irrigation of pericardial space

Pericardial drain after epicardial ablation

Pericardial lavage for several hours with steroid solution after drain is placed (clamp drain)

Anticoagulation – Resume anticoagulation of choice (unfractionated heparin, DOAC) evening of day of surgery if not bleeding; resume home regimen in AM of POD 1.

Volume management – Diuresis as needed

Pericarditis management – Options include colchicine, steroids (IV in-hospital, oral at discharge), NSAIDs

Rhythm Control – Resume pre-op AADs on evening of day of procedure for at least 60-90 days (blinking period)

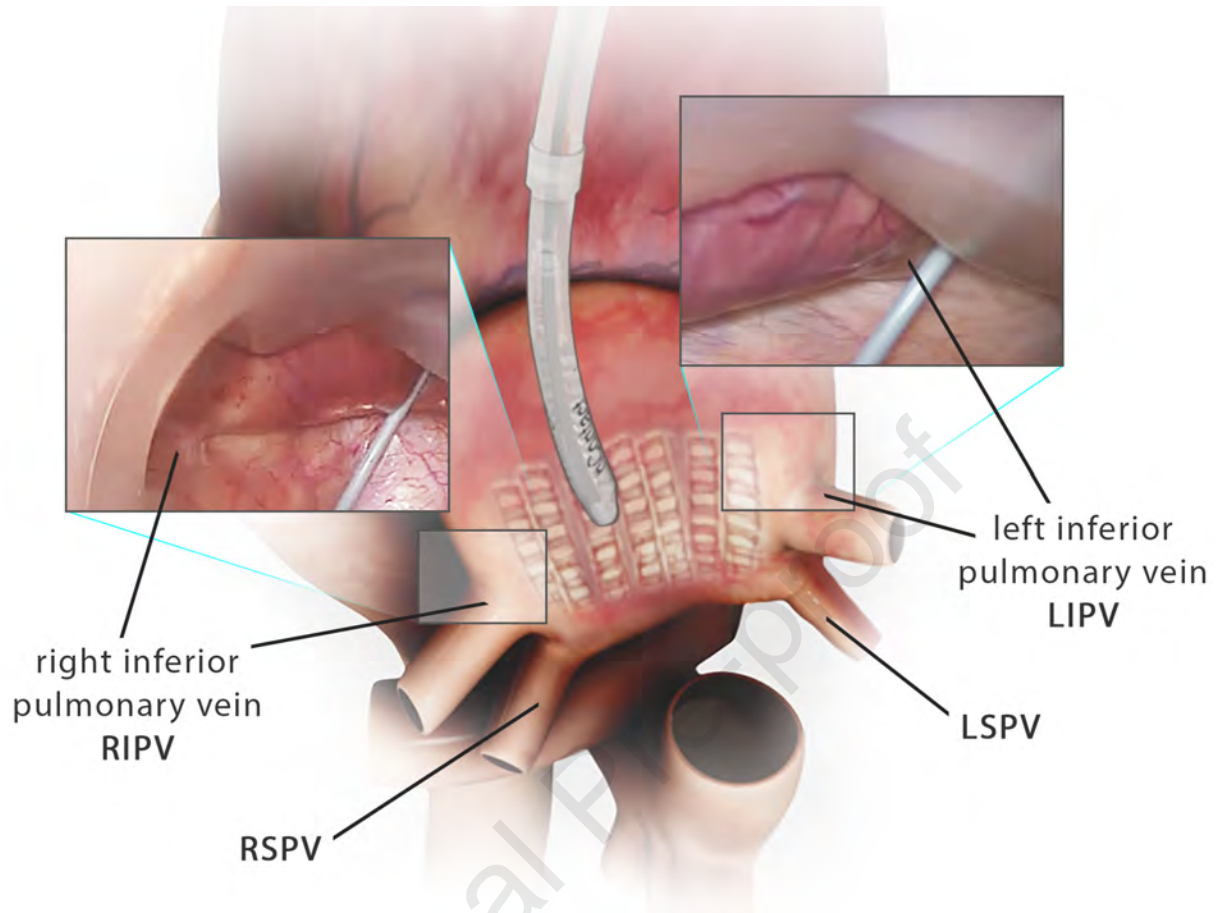
Post-Operative

Considerations

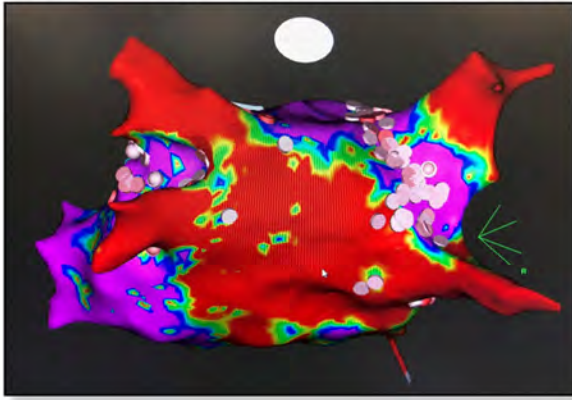
Surgical follow-up (1-4 weeks)

Transthoracic echocardiogram – Evaluate late pericardial effusion (2-4 weeks)

Electrophysiology follow-up (1-3 months)



A Post-epicardial/pre-endocardial



B Post-epicardial/post-endocardial



Journal Pre-proof