Balancing Arrhythmia Freedom and Complications: A Single Center Experience with Vein of Marshall Ethanol Infusion as an Adjunct to Catheter Ablation of Atrial Fibrillation

Jordan Leyton-Mange S[1], Kunal Tandon[1], Edward Sze Y[1], Charles Carpenter M[1], and Henry Sesselberg W[1]

[1]Maine Medical Partners MaineHealth Cardiology

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Abstract

Since the discovery of pulmonary venous triggers,[1](#ref-0001) catheter ablation with pulmonary vein isolation (PVI) has matured as an important therapy for patients with atrial fibrillation (AF). However despite advances in ablation technology, for non-paroxysmal forms of AF, outcomes remain suboptimal with PVI alone.[](#ref-0002)2 ,3 Adjunctive strategies addressing the atrial substrate or targeting of non-pulmonary vein triggers have not shown consistent efficacy across studies and may carry additional complication risks or higher rates of recurrent organized atrial tachycardias. Recently, ethanol infusion into the vein of Marshall (VOM) has gained popularity with the publication of the VENUS randomized trial[4](#ref-0004) and the positive accumulating experience reported from a single center in Bordeaux.[](#ref-0005)5 ,6 However, adoption has been tempered due to the technical requirements of the procedure and unclear dominant mechanism of putative benefit. Thus, more widespread experience is needed to clarify the real-world impact on procedural success. This report aims to describe a single center experience with VOM ethanol infusion over three years, with description of technical approach, associated procedural success rates, and complications.

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Short title: Maine Experience with Vein of Marshall Ethanol Infusion

Authors: Jordan S Leyton-Mange MD[1,2]*, Kunal Tandon, MD[1,2], Edward Y Sze, MD[1,2], Charles M Carpenter, MD[1,2], and Henry W Sesselberg MD[1,2]

Affiliations:

[1]Department of Cardiology, Maine Medical Center, Portland, ME 04102

[2]Maine Medical Partners MaineHealth Cardiology, Scarborough, ME 04074

Contact Information:

*Correspondence: Jordan Leyton-Mange, MaineHealth Cardiology, 96 Campus Drive, Scarborough, ME 04074, jordan.leyton-mange@mainehealth.org

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VOM, vein of Marshall, AF ablation

Introduction

Since the discovery of pulmonary venous triggers,[1] catheter ablation with pulmonary vein isolation (PVI) has matured as an important therapy for patients with atrial fibrillation (AF). However despite advances in ablation technology, for non-paroxysmal forms of AF, outcomes remain suboptimal with PVI alone.[2,3]Adjunctive strategies addressing the atrial substrate or targeting of non-pulmonary vein triggers have not shown consistent efficacy across studies and may carry additional complication risks or higher rates of recurrent organized atrial tachycardias. Recently, ethanol infusion into the vein of Marshall (VOM) has gained popularity with the publication of the VENUS randomized trial[4] and the positive accumulating experience reported from a single center in Bordeaux.[5,6]However, adoption has been tempered due to the technical requirements of the procedure and unclear dominant mechanism of putative benefit. Thus, more widespread experience is needed to clarify the real-world impact on procedural success. This report aims to describe a single center experience with VOM ethanol infusion over three years, with description of technical approach, associated procedural success rates, and complications.

Material and Methods

Study population

We retrospectively analyzed all atrial ablation cases wherein VOM ethanol infusion was attempted between August of 2019 and May of 2022 at Maine Medical Center (Portland, ME). This study was approved by the Intuitional Review Board and performed in accordance with the Declaration of Helsinki.

Catheter ablation

Ablations were performed under general anesthesia with low tidal volume ventilation and uninterrupted anticoagulation. Three dimensional guidance was performed with the CARTO 3 system (Biosense Webster). Heparin infusion was utilized to maintain an activated clotting time of 350 seconds. Pacing from either the coronary sinus (CS) or right ventricle was performed to reduce the stroke volume and variability in cardiac motion. All procedures utilized irrigated radiofrequency with the STSF catheter aiming for interlesion distances of 4mm (Biosense Webster). In addition to VOM ethanol infusion, the standard lesion set for patients with persistent AF in this study consisted of PVI, left atrial posterior wall isolation (PWI), CS isolation, posterior mitral isthmus line (MIL), and a cavotricuspid isthmus line (CTI) (Figure 1). The mitral isthmus was ablated with air-filled balloon occlusion of the CS in almost all cases to improve lesion transmurality near the annulus.[7] In the subset of patients both with persistent and occasionally paroxysmal AF wherein VOM ethanol was not preplanned and rather performed *ad hoc* (most commonly for induced mitral annular flutter in patients with myopathic low voltage regions, Table 1), MIL, CS isolation, and PWI was still systematically performed. The sought end points for CS isolation and PWI included elimination of local electrograms and lack of pace capture of the atrium with high output bipolar pacing from within the isolated structure (20mA, 2msec). The proximal third of the CS was not ablated to avoid iatrogenic atrioventricular (AV) block. For the first half of the enrollment period, luminal temperature monitoring was used for esophageal protection and occasionally, PWI was avoided in favor of a reinforced roof line if the esophageal risk was deemed too great because of esophageal heating or close proximity to the posterior wall on intracardiac echo (ICE). Towards the latter half of the study, patients underwent active esophageal cooling at 4°C (Enso ETM, Attune Medical, Chicago, IL). Rarely, CTI ablation was avoided if typical atrial flutter was not inducible and the appearance of the region on ICE appeared anatomically challenging. Adenosine was used to assess for dormant conduction and in select procedures, isoproterenol infusion was used to disclose non-PV foci.

VOM ethanol infusion

VOM ethanol infusion was performed prior to transseptal puncture and systemic heparinization in the first several cases but following left atrial mapping in the subsequent ones. From a femoral approach, the CS was cannulated with an SL-2 sheath over a deflectable decapolar catheter. A floppy tip straight 0.35”

guidewire (MagicTorque, Boston Scientific or Wholey wire, Medtronic) was advanced passed Vieussens valve into the great cardiac vein to retain access and a venogram was performed through the sheath in the right anterior oblique projection to highlight the VOM. Often the VOM was not identifiable on venography but was subsequently found either proximal to the sheath tip or just proximal to Vieussens valve. An IMA guide catheter was carefully advanced over another 0.35" guidewire into the CS. The guidewire was then exchanged for an 0.14" angioplasty wire preloaded with an over the wire balloon to occlude the proximal VOM (1.5mm-2.5mm range though typically 2mm, Emerge Dilation catheter, Boston Scientific). An 0.14" PT Graphix wire (Straight tip, 300cm, Boston Scientific) was used for the initial cases but all subsequent ones were performed with the low tip weight Suoh wire (0.3 gf, Asahi) to virtually eliminate the risk of wire perforation. After VOM ethanol infusion, CS ablation was systematically performed through the SL-2 sheath. A rare subset of cases were performed from a superior approach, including the initial case in the series as well as subsequent ones wherein the VOM could not be stably cannulated from a femoral approach. After proximal VOM occlusion, a selective venogram was performed and up to 4 injections of anhydrous ethanol were performed of 1-3 cc, each over 30-60 seconds. Echogenicity was usually noted on ICE and a low voltage zone of varying size and confluency was demonstrated on electroanatomical mapping. VOM venograms were not systemically performed between ethanol injections, fearing additive risk of dissection of the VOM from viscous iodinated contrast unless there was suspicion of poor occlusion, balloon movement, or dissection, particularly in the absence of a significant ethanol response. Due to a series of dissections noted on initial venography and the delayed pericardial effusions noted in this study, for the final twenty one cases in the series, systematic use of the initial VOM venogram was abandoned unless prompted by concern of poor ethanol delivery on imaging or mapping due to the perceived dissection risks from brisk injections of contrast.

Outcomes

Recurrences were adjudicated by the study authors based upon rhythm tracings in the medical record. Tracings from standard electrocardiography, wearable rhythm monitoring, and recordings from cardiac implantable electronic devices (CIED), whether scheduled or symptom triggered, were permitted and assessed. Recurrence was defined as recurrent atrial fibrillation, atrial flutter, or atrial tachycardia of at least 30 seconds duration, after at least 90 days post procedure. Complications were determined from the medical record. Tamponade was defined as pericardial effusion requiring pericardiocentesis. Survival probabilities were computed with a product limit (Kaplan Meier) approach, censoring patients at the time of recurrence.

Results

Procedural details

A total of 129 patients underwent attempted VOM ethanol infusion during the study period (Table 1). The average age was 64.3 years and 67.4% were male. Ninety were initial procedures for AF and 39 were redo procedures. Of the latter group, 56% had permanent PVI upon initial intraprocedural mapping. Most VOM infusions were preplanned, but a substantial proportion, including 26% in the group of initial procedures, were *ad hoc* . All but one of these were performed a*d hoc* to facilitate block for induced mitral annular flutter, with the additional one done in the case of a suspected ligament of Marshall trigger for AF after PVI was completed. The *ad hoc* group encompassed nearly the entirety of patients with paroxysmal AF undergoing VOM infusion during an index procedure. Ablation was restricted to the standard lesion set as depicted in Figure 1 in 88% of the patients taken for an initial AF ablation but the majority of redo cases had additional lesions, most commonly SVC isolation/ablation (69%).

The success rate of VOM infusion was 90%, though improved in follow-up from a 76% success in the initial years of the study to 100% in 2022. Reasons for failure of ethanol delivery in twelve patients included failure to cannulate the CS (1), a left persistent superior vena cava (SVC) (1), a wire perforation with avoidance of ethanol delivery (1), targeting of the incorrect vein (2), failure to cannulate the VOM (3), and failure to identify the VOM (4). Total case fluoroscopy averaged 18.8 minutes but decreased during the study from 34.6 minutes during the first two years of the study to 10.5 minutes during 2022 (Figure 2). VOM perforation

occurred in two patients (1.6%) including one wherein ethanol was not delivered. VOM dissection occurred in 8.5% of patients. These events and procedural success are depicted by procedure order in Figure 2A. All attempts at acute mitral isthmus block were successful, irrespective of whether the VOM ethanol infusion was completed.

Efficacy

A total of 94 patients had at least one rhythm assessment at least 90 days post procedure and were included in analysis of efficacy outcomes. The follow-up duration ranged from 3.0 to 30.1 months with an average duration of 9.5 months. Rhythm assessments were made with CIEDs in 17% of patients, prescribed wearable monitors in 41.5%, and standard electrocardiography alone in 41.5% of patients. The overall recurrence rate was 14%. Only five (5%) patients experienced clinical failure, a subjective assessment by the authors conveying failure of arrhythmia control (on or off antiarrhythmic drugs) or a need for further procedures. The majority of the others were modest and detailed in a Supplemental Table 1. Survival probabilities are shown in Figure 3, estimating an 80% arrhythmia free survival at twelve months following the initial VOM infusion ablation. The respective arrhythmia freedom probabilities at twelve months were 80% when restricting analysis to initial procedures (N=65 procedures), and 79% when only analyzing persistent AF patients undergoing an initial procedure (N=54 procedures).

Four patients were taken for redo ablations after the VOM ethanol infusion procedure. Two of these patients experienced atypical flutter, both corresponding to circuits involving the posterior wall. The mitral isthmus required reablation in one of those patients though it was not mediating the recurrent arrhythmia. The other two patients each experienced recurrent paroxysmal AF. The first required early reablation for repeated cardioversions in emergency room settings with poorly controlled rates. In this case, the left veins, posterior wall, and mitral isthmus all required reablation. Unfortunately he continued to have poorly controlled rapid AF and underwent AV nodal ablation. The other patient had a completely intact initial lesion set (standard lesion set plus SVC isolation) but an additional right atrial trigger was noted with isoproterenol and successfully ablated. This was complicated by sinus nodal injury necessitating a pacemaker. Among these four patients, only the one requiring the AV nodal ablation has had documented recurrence following the redo ablation (Supplemental Table 1).

Complications

Eight patients (6.3%) experienced procedural complications (Figure 2B, Table 2). These were noteworthy for five cases of cardiac tamponade. One was intraprocedural in a patient undergoing a fourth procedure for repeated and refractory atypical flutters requiring emergency room presentations. PVI was noted on initial mapping but no non-PV foci or inducible arrhythmias were seen on high dose isoproterenol. VOM ethanol, CS isolation, lateral MI ablation, and SVC isolation were performed prior to the notice of an accumulating effusion thought secondary to right atrial perforation. Pericardiocentesis was performed and ablation of the CTI was deferred. It is noteworthy that he has had good arrhythmia control over 24 months of follow-up except for a single presentation of typical atrial flutter to the emergency room. An additional four patients (3.1%) had a delayed presentation of tamponade (Figure 4), presenting at 12 to 33 days post procedure. One of these four patients had a dissection of the VOM during initial venography and another one of the patients had a possible VOM perforation. Interestingly, two of these patients had unrevealing transthoracic echocardiograms (at three and twelve days post procedure) done for other clinical reasons in the weeks before presenting with tamponade (Figure 4). On a third patient, the hematocrit on the pericardial fluid was assessed due to a dark red appearance and was found to be less than 1%.

The only other notable complication was sinus injury, occurring in three patients. In one, sinus arrest was noted immediately upon the initial VOM ethanol infusion. VOM venography in that case revealed a typical branching pattern without discernable collaterals to the right atrium/SVC or left atrial roof. Some low voltage regions were seen in the right atrium in the sinoatrial region. The other two sinus injury complications were from direct radiofrequency, both in patients undergoing third AF procedures, one from empiric SVC isolation and the other from ablation of a high cristae AF trigger. All three patients recovered some sinus function

but due to pauses or chronotropic incompetence underwent pacemaker implantation in the days to weeks that followed. No additional complications including PV stenosis, stroke, esophageal injury, AV block, left atrial appendage isolation, or anaphylaxis from ethanol infusion were noted. Two deaths occurred which were each judged to be unrelated to the procedure. One patient died 40 days post procedure due to intractable bleeding around rupture of an aortic graft remote from the sites of ablation or trans-septal puncture. The other experienced persistent AF recurrence eleven months post procedure and died the following month of intractable mixed cardiogenic and distributive shock.

Discussion

In this study, we report the feasibility, efficacy, and complication risks related to a moderate volume of VOM ethanol infusions for AF ablation. We demonstrate that VOM ethanol infusion has a learning curve with improved success rates and lowered fluoroscopy times with accumulated experience, even across years of reasonable procedural volume. Rates of VOM perforation, dissection, and overall ethanol infusion success rate were remarkably similar to published reports in a highly experienced center.[8]

A majority of patients had a CIED or wearable monitors to assess arrhythmia recurrence. In the context of a pandemic follow-up system that was often limited to telemedicine without formal rhythm assessments, and the fact that several procedures were performed in the few months leading up to this study, the average follow-up duration was 9.5 months. We acknowledge that with longer follow-up durations and/or continuous rhythm monitoring, more recurrences may have been detected. Nonetheless, we observed extremely low clinical failure and redo procedure rates, and a one year probability of 80% for arrhythmia freedom. This is prominently viewed in light of a significant proportion of long-standing persistent AF patients and the majority of redo procedures enrolled featuring documented permanent PVI. The left atrial size in this study is similar to that of the CONVERGE trial of hybrid ablation,[11] although the proportion of long-standing persistent AF patients is much lower. Studies of similar success rates in persistent AF patients with less comprehensive ablation approaches have only featured subjects with much smaller atrial sizes.[12]Unfortunately, the degree that any improved efficacy is due to the VOM ethanol infusion per say is not possible to assess by this analysis. The standard lesion set in this study encompassed isolation of the posterior wall, CS, mitral isthmus, and cavotricuspid isthmus in almost all cases. Additional ablation beyond this was not insignificant either, particularly in redo procedures. Nonetheless, other studies have questioned the value of these approaches, particularly for ablation lines which were not found to be helpful in a large randomized trial.[3] Even if the VOM ethanol infusion dominates as the marginal difference accounting for the success in this cohort, the mechanism of benefit remains unclear. In VENUS, the benefit was constrained to the patients with successful mitral isthmus block.[13]It is possible that the VOM ethanol infusion merely ensures more permanent mitral block[14-16] or isolation around the left pulmonary vein antra. However additional effects of autonomic denervation[17], debulking of atrial mass, or direct suppression of ligament of Marshall AF triggers[18] are plausible as well.

Despite excellent arrhythmia freedom in our cohort, review of these patient outcomes unveiled important safety concerns that also may differ in frequency from those after PVI alone. To the best of our knowledge, we note the first demonstration of sinus nodal injury directly from VOM ethanol infusion. The underlying mechanism is not clear. Although not apparent on venography, we suspect that collateral vessels were present and delivered ethanol to the sinoatrial region. We did not observe any AV block, left atrial appendage isolation, or anaphylaxis that have been described with VOM ethanol.[8] With respect to the important complication of tamponade we demonstrated a high rate of delayed pericardial effusions. Two of the four patients in this cohort with delayed effusions had unrevealing echocardiograms days after their ablations, only to later present with pericardial tamponade. A third had a hematocrit less than 1% on the pericardial fluid despite a bloody appearance. These findings suggest that the dominant mechanism of delayed tamponade in these cases was inflammatory pericarditis rather than hemorrhagic. Early on in our experience we adjusted our procedural technique to minimize CS related complication. A retention wire is used through the CS guide sheath to avoid CS wall trauma and the IMA catheter is inserted over a wire. Furthermore, we probe for the VOM with a low tip weight angioplasty wire (Suoh wire, Asahi) rather than localize the VOM with contrast puffs. This should lower the risk of VOM perforation/dissection or CS dissection and while we have neared

a 100% success rate with VOM ethanol infusion, we have noted a higher rate of delayed tamponade than reported previously in the VENUS study or Bordeaux experience.[8,12]The rate is more in line with pericardial effusions in the CONVERGE study of hybrid surgical ablation.[3] While the low total number of cases leaves open the possibility that our increased rate of delayed tamponade is due to chance alone, interestingly, all four cases of delayed tamponade in our series occurred in the second half of our cohort of patients. We have postulated that as we have become more facile with the procedure, perhaps a brisker workflow with faster ethanol infusions may have contributed. Thus while we typically still instill four ethanol injections, we have minimized the total volume of ethanol infused from an average of 10ml to 4-5ml, and each injection is instilled slowly over 60 seconds. In addition, in order to avoid contrast induced hydraulic dissections of the VOM, we do not any longer systematically perform VOM venography unless there is uncertainty of the vein identity (non-VOM), the quality of venous occlusion as evidenced by balloon movement, or lack of demonstrable ethanol effects on mapping or ICE. Further study is required to tell if this approach will lower the rate of delayed effusions related to VOM ethanol. Importantly, noting this complication has recalibrated our judgement and patient selection in deciding when to employ the technique.

This study is limited by its retrospective nature, selected population, and the fact that all cases were performed at a single center with a single operator. As advances in ablation techniques and energy sources bring us closer to ensuring permanent PVI,[9,10]the role for VOM ethanol and other adjunctive techniques for AF ablation may take on greater importance. Currently, there is a paucity of published experience with VOM ethanol infusion and it is rarely performed outside of select centers of excellence. We believe that cases series such as this add important insights to the literature of this technique, informing operators already performing or considering VOM ethanol infusion in the future.

Conclusion

In summary, we present the experience of a moderate volume of VOM ethanol infusions in routine practice of AF ablation from a single medical center. Our demonstration of the feasibility of growing this program in a previously inexperienced center should allay trepidation to other operators or readers considering adopting this technique into their repertoire. While the high efficacy is laudable, the rate of delayed pericardial effusions should be noted and operators prepared for this complication with early echocardiographic follow-up and for informed consent discussions with patients. Further study of VOM ethanol infusion is needed to determine the marginal benefit and risks across centers.

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Table 1 – Patient characteristics and procedural details

Abbreviations: pAF – paroxysmal AF, persAF – persistent AF, LSPAF – long-standing persistent AF, AVNRT – AV nodal reentrant tachycardia.

Total patients *Paroxysmal, Persistent, Long-Standing Persistent*
Average age (years)

Total patients *Paroxysmal, Persistent, Long-Standing Persistent*
Male
Left atrial diameter, avg (mm)
Index AF ablations *Preplanned VOM Ad hoc VOM Standard lesion set only SVC ablation/isolation Additional arrhythmia*
Redo Procedures 1 prior; 2 prior; 3 prior *Preplanned VOM Ad hoc VOM Permanent PVI upon initial mapping Standard le*
VOM ethanol infusion success *2019-2020 success 2022 success*
Reasons for VOM Ethanol failure *CS could not be cannulated Left persistent SVC Wire perforation Incorrect vein targeted*
VOM Dissection
VOM Perforation
Fluoroscopy, avg (min) *2019-2020 2022*

Table 2 – Procedural efficacy and complications

Patients with rhythm assessment > 90 days follow-up
Follow-up duration (months, range) Median Average
Assessment methods *Standard electrocardiography only Wearable monitor CIED*
Recurrence *After final procedure*
Clinical failure *After final procedure*
Redo procedure after VOM *Recurrence rate after subsequent redo Ultimate AV nodal ablation*
Procedurally related complications *Intraprocedural tamponade Delayed tamponade Sinus injury Direct result of VOM ethan*

Figure 1

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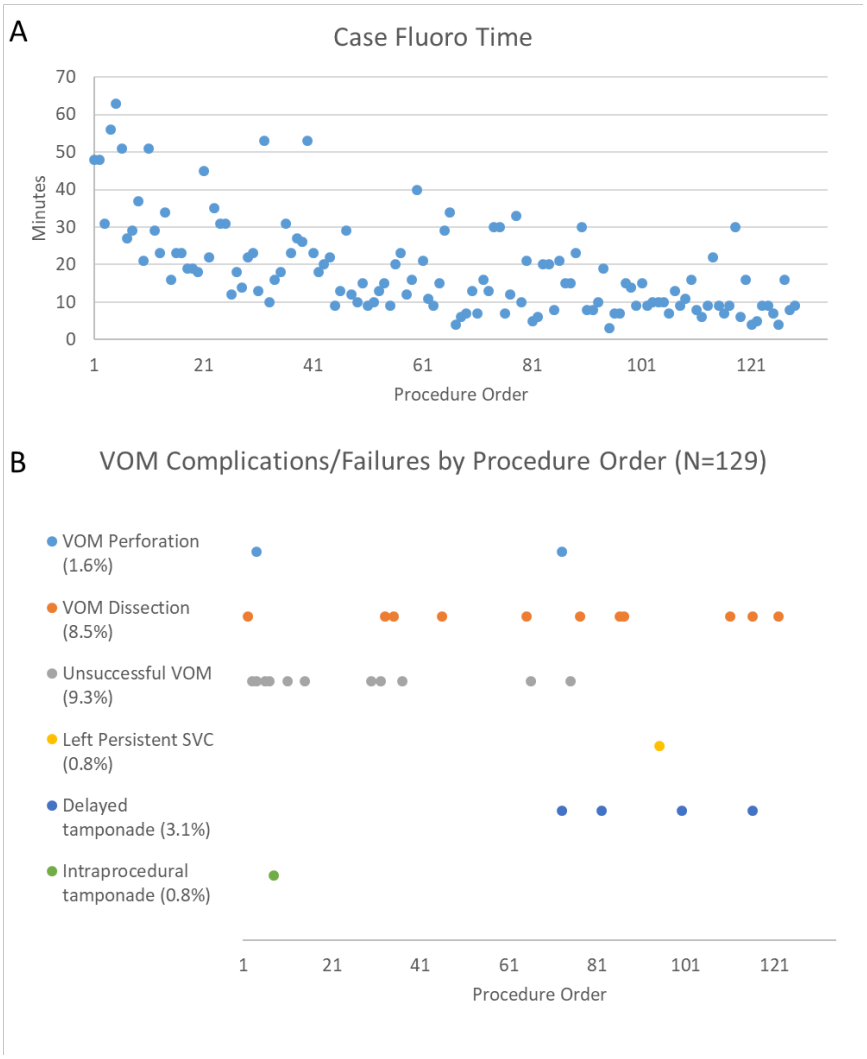
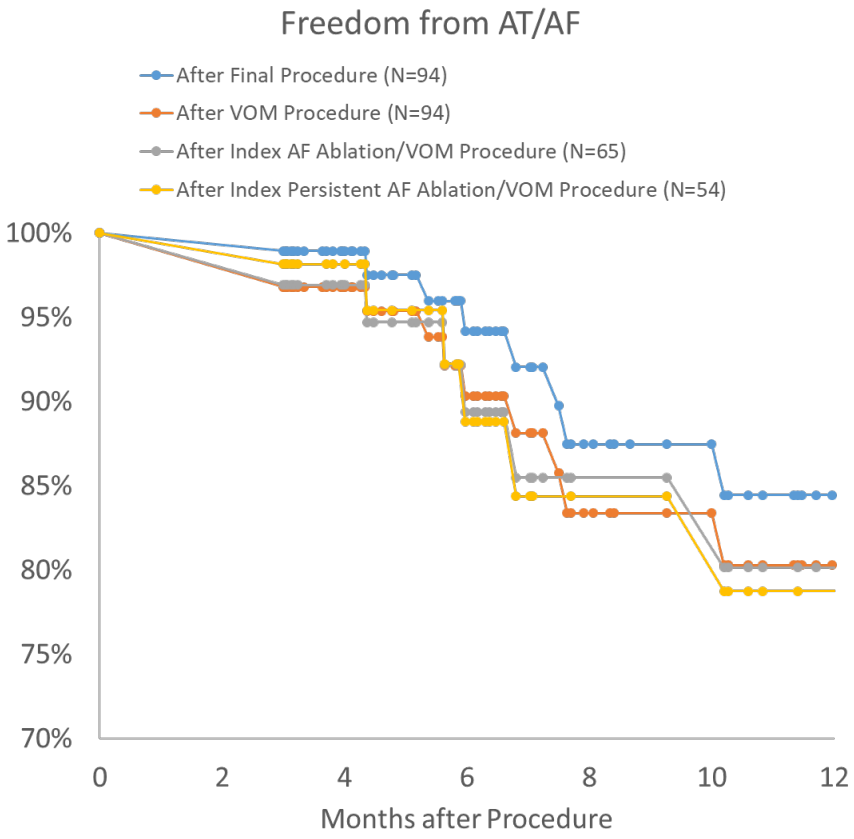
Three dimensional maps depicting the standard lesion set used for patients in this study. In addition to VOM ethanol infusion, PVI, PWI, CS isolation, MIL and CTI lines were systematically performed.

Figure 2



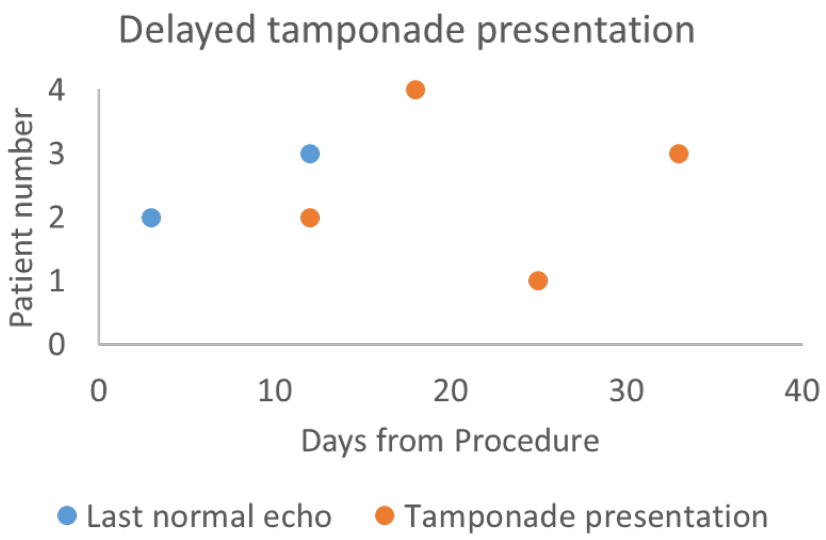
(A) Total case fluoroscopy time and (B) VOM ethanol infusion complications catalogued by procedure order (N=129).

Figure 3



Kaplan Meier survival probabilities from atrial tachyarrhythmias for 12 months following ablation after the final ablation procedure including four patients that had redo ablations following the VOM procedure (blue, N=94), after the VOM procedure (N=94), after only initial AF ablations (N=65), and after only initial ablations performed for patients with persistent AF (N=54).

Figure 4



Timing post ablation for four patients with presentations of delayed tamponade. Patients 2 and 3 had normal echocardiograms post ablation in the weeks leading up to presenting with tamponade.

Supplemental Table 1 – Details of recurrences

Patient number	Type of AF treated	Timing of recurrence (months)	Clinical Failure of 1st procedure	Recurrence det
1	PersAF	14.1	N	Single episode
2	PersAF	4.4	N	Recurrence, lat
3	PersAF	6.0	N	3 pAF recurren
4	LSPAF	6.8	N	Single 14 hour
5	PersAF	10.2	Y	Recurrent pers
6	LSPAF	3.0	Y	Recurrent atyp
7	PersAF	5.6	Y	Recurrent atyp
8	pAF	3.0	Y	Recurrent atria
9	pAF	3.0	Y	Recurrent paro
10	pAF	7.5	N	Recurrent typic
11	LSPAF	5.4	N	Presented for s
12	PersAF	16.7	N	Stopped dotetil
13	PersAF	7.6	N	Single 90 secon

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