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Catheter Ablation of Atrial Fibrillation in Patients with Hardware in the Heart : Septal Closure Devices, Mechanical Valves and More

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Abstract

Patients with mechanical "hardware" in the heart, such as those with mechanical cardiac valves or atrial septal closure devices, represent a population at high risk of developing AF. Catheter ablation of AF in these subjects might represent a challenge, due to the perceived higher risk of complications associated with the presence of intracardiac mechanical devices. Accordingly, such patients were excluded or poorly represented in major trials proving the benefit of catheter ablation for the rhythm-control of AF. However, recent evidence supports the concept that catheter ablation procedures might be equally effective in these patients, without a significant increase in the risk of procedural complications. This review will summarize the current state-of-the-art on catheter ablation of AF in patients with mechanical "hardware" in the heart.

Introduction

Atrial fibrillation (AF) is the most common arrhythmia encountered in clinical practice, affecting 1% of the general population and up to 10% of patients over 80 years of age.¹ Radiofrequency catheter ablation has been demonstrated effective to achieve long-term sinus rhythm maintenance in a large proportion of patients with drugrefractory AF.²

Patients with mechanical "hardware" in the heart, such as those with mechanical cardiac valves or atrial septal closure devices, represent a population at high risk of developing AF. Remarkably, such patients were excluded or poorly represented in major trials proving the benefit of catheter ablation for the rhythm-control of AF. Recent evidence supports the concept that catheter ablation procedures might be

Disclosures:

Corresponding Author: Pasquale Santangeli, MD Hospital of the University of Pennsylvania 8 Gates Pavilion - Cardiology, 3400 Spruce St Philadelphia, PA, 19104 equally effective in these patients, without a significant increase in the risk of procedural complications. This review will summarize the current state-of-the-art on catheter ablation of AF in patients with mechanical "hardware" in the heart.

Septal closure Devices

Current Evidence

Percutaneous septal closure is an appealing therapeutic option for patients with either a patent foramen ovale (PFO) or an atrial septal defect (ASD). In both cases, the techniques essentially consist of the introduction of one of various available septal closure devices (usually through femoral venous access) and its deployment at the interatrial septum to close off the interatrial communication. Indications for this procedure are currently the subject of a heated debate in patients with a PFO,^{3,4} while they are becoming broader in ASD patients,⁵⁻⁷ who are at an increased risk of AF and remain so even after ASD closure.⁸⁻¹¹ In patients with interatrial septal repair, AF ablation is perceived as more challenging because the presence of a septal closure device may make transseptal access more difficult. Success was first reported in 2008 by Zaker-Shahrak and colleagues¹² in two patients who had undergone PFO closure with an Amplatzer[™] plug (AGA Medical Corporation, Plymouth, MN, USA). Transseptal puncture was performed through a portion of the native interatrial septum

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just below the caudal rim of the device, without periprocedural complications.

In 2008 Lakkireddy and colleagues¹³ reported a case-control study on 45 patients with a previous ASD or PFO repair and 45 matched controls. Of the former category, 18/45 (40.0%) had undergone percutaneous repair with a CardioSEAL® device (NMT Medical Inc, Boston, MA, USA), 5/45 (11.1%) with an Amplatzer device, while 22/45 had undergone surgical repair. In all cases AF ablation supported by intracardiac echocardiography and fluoroscopic guidance was feasible and safe, and was not associated with prolongation of either total procedural times or fluoroscopy times compared to controls. Double transseptal puncture was performed through available infero-posterior portions of the native interatrial septum in all 23 patients with a septal closure device. At a mean follow up of 15±4 months, 76% of the 45 patients with previous interatrial septal repair remained free from AF recurrences. No subgroup analysis was presented on percutaneous closure cases compared to surgical repair cases and/or to matched controls.

In 2011 Santangeli and colleagues¹⁴ reported a more specific case series of 39 patients with no prior AF ablation and a previously corrected isolated ostium secundum ASD, including 32 patients with an Amplatzer plug and 7 with a CardioSEAL device. No patient had evidence of interatrial shunting before the procedure. All underwent ablation on therapeutic warfarin,^{15,16} under general anesthesia,¹⁷ with the fundamental support of intracardiac echocardiography as well as fluoroscopic guidance. In 35/39 patients (89.7%) double transseptal puncture was performed in a portion of the native septum anterior to the septal closure device; in 33/35 cases (94.3%) puncture was aided by applying radiofrequency to the transseptal needle during interatrial septal tenting. In the remaining 4/39 patients (10.3%) double transseptal puncture was performed directly through the device (an Amplatzer plug in all four) because no portion of the native septum was available. Procedural endpoints were met in all cases, but performing transseptal puncture directly through the closure device took much longer (4.3±0.4 versus 73.6±1.1 minutes, p<0.001), was associated with longer fluoroscopy times (80±8 versus 122±5 minutes, p<0.001) and longer procedural times (3.1±0.3 versus 4.1±0.2 hours). No significant periprocedural complications occurred. Post-ablation transthoracic echocardiography showed minimal interatrial shunting in 10/35 (28.6%) of patients punctured through their native septum, a rate that is compatible with previous experiences with double transseptal puncture in patients without septal closure devices;¹⁸⁻²⁰ no shunting was found in the 4 patients punctured through the device. Contrast-enhanced echocardiography (with the Valsalva maneuver) performed 3-6 months after ablation found no residual interatrial shunting in any patient.

Data from this 2011 study thus support the feasibility and safety of transseptal puncture in patients with a septal closure device, although they only apply to isolated ASD (as opposed to more complex congenital heart disease). Although spontaneous closure in the native septum has been well reported in the past,^{18, 20, 21} the mechanism which prevents residual intra-atrial shunting after puncture through the woven polymer mesh of septal closure devices remains to be elucidated. A possible explanation is microthrombosis within the polyester baffles, which has been shown in previous animal studies to become completely covered in protein and cellular layers within three months.²² However, puncture through septal closure devices

is not a risk-free endeavor and some cautions are still warranted in generalizing these results to other Institutions and operators.²³ On one hand, the fact that the study did not routinely evaluate post-procedural iatrogenic interatrial shunting with transoesophageal echocardiography might have underestimated the incidence of smaller iatrogenic shunts; on the other hand, even in that case it would have still remained unclear whether such smaller shunts would have held any clinical significance. Also, only Amplatzer devices were punctured: no evidence exists on puncture through other septal occluder types.

In 2012 Chen and colleagues²⁴ reported single transseptal puncture directly through an Amplatzer device facilitated by an angioplasty balloon inflated to 16 atm. Transseptal puncture took 52 minutes, no periprocedural complications occurred, and a post-ablation transthoracic echocardiogram (with the Valsalva maneuver) showed no residual interatrial shunting.

In trying to assess whether puncture through the remaining portion of the native interatrial septum is possible, a 2012 paper by Wagdi and Alkhadi²⁵ retrospectively analyzed cardiac CT studies (performed for chest pain, suspected or known coronary artery disease) from 20 patients who had previously undergone percutaneous septal closure (12 Amplatzer, 4 Atriasept[™], 3 Figulla[™], 1 Solysafe[™]) due to PFO (15/20) or ASD (5/20). The minimal distance between the device and the atrial floor was calculated at the 6-o'clock and 7:30 positions, arbitrarily choosing 6 mm as the minimal distance that was felt to be "safe" for puncture in the native septum. They found such a "safe" rim in 10/20 patients and, interestingly, reported that neither device size nor atrial dimensions predicted whether such a "safe" rim existed. Unfortunately, this remained a purely observational study, as no patient then underwent AF ablation. Therefore, there is no evidence basis to state whether pre-ablation cardiac CT actually helps predict the feasibility of transseptal puncture in the native septum in these cases.

State of the Art

In summary, current published evidence suggests that transseptal puncture in patients with a septal closure device is feasible and safe either through the native septum or directly through the device, although this remains a complex and time-consuming procedure even in experienced hands.

Mechanical Mitral Valve Prostheses

The risk of AF is increased in mitral valve disease²⁶ and specifically after mitral valve replacement surgery,²⁶⁻²⁹ but the presence of the mechanical mitral valve prostheses (MMVP) raises concerns over valve damage³⁰ or catheter entrapment³¹⁻³³ during LA ablation procedures. While there are no randomized controlled trials on this subject, three observational studies³⁴⁻³⁶ on AF ablation and one on peri-mitral flutter (PMFL)³⁷ ablation have been published (Tables 1 and 2). We also recently published a pooled analysis of such data,³⁸ aggregating a total population of 178 cases and 285 controls.

Feasibility

The four observational studies confirm the feasibility of LA ablation procedures in MMVP patients, although our pooled analysis revealed longer procedural times in MMVP patients than in controls (weighted mean difference: +24.5 minutes).³⁸ Only in one patient enrolled in the study by Lang and colleagues,³⁴ ablation was aborted due to impossibility to perform transseptal puncture, which the

Table 1: Patient populations and procedural features in studies for left atrial ablation in patients with a mechanical mitral valve prosthesis

Study	Arrhythmia	Population	Peri-procedural anticoagulation	Technology	Ablation procedure types (cases vs controls)	Fluoroscopy time in minutes (cases vs controls)
Lang et al ³⁴ (Italy, 2005)	AF	26 cases (50% parox.) 52 controls (50% parox.)	LMWH bridging	CARTO mapping Non-irrigated ablation catheter (No circular mapping catheter)	CPVA (all patients) MIL (93% vs 94%) Posterior/roof line (81% vs 81%)	35±21 vs 21±15 (p<0.001)
Lakkireddy et al ³⁵ (USA, 2011)	AF	50 cases (41 MMVP, 5 mechanical aortic valve, 4 both) (40% parox.) 50 controls (40% parox.)	Warfarin with therapeutic INR	Intracardiac echocardiography Circular mapping catheter CARTO or NavX mapping Irrigated ablation catheter	 PVAI (all patients) CFAE ablation (all non-paroxysmal AF cases) Epicardial ablation from within the coronary sinus (all non-paroxysmal AF cases Non-PV triggers (if found with isoprenaline infusion) Further ablation lines (see original paper), including MIL (20% of cases) 	60±17 vs 53.8±6.8 (p<0.01)
Hussein et al ³⁶ (USA, 2011)	AF	81 cases (70.4% parox.) 162 controls (67.3% parox.)	Warfarin with therapeutic INR	 Intracardiac echocardiography Circular mapping catheter Unspecified electroanatomical mapping (only for flutter ablation) (Unspecified ablation catheter) 	 PVAI (all patients) Superior vena cava (all patients) Non-PV triggers (44.4% vs unspecified) Further ablation lines (<50%: see original paper), including MIL. 	37±12 vs 17±8 (p<0.01)
Mountantonakis et al ³⁷ (USA, 2011)	PMFL ± AF	21 cases (9 MMVP, 21 mitral annuloplasty) 21 controls	Warfarin with therapeutic INR	 Intracardiac echocardiography CARTO or NavX mapping Circular mapping catheter Irrigated ablation catheter Steerable sheath (81% vs 71%) 	 PVAI + MIL (all patients) Epicardial ablation from within the coronary sinus (43% vs 68%) LAA stump ablation (unspecified) 	Not reported

AF = atrial fibrillation; PMFL = peri-mitral flutter; LMWH = low molecular weight heparin; MIL = mitral isthmus line; PVAI = pulmonary vein antral isolation; CFAE = complex fractionated atrial electrograms; LAA = left atrial appendage.

authors attributed to cardiac rotation.

Radiation Exposure

Radiation exposure is a significant concern in electrophysiology procedures. Our pooled analysis found that procedures required longer fluoroscopy times in MMVP patients than in controls (weighted mean difference of +13.5 minutes).³⁸ All three studies on AF ablation reported this difference,³⁴⁻³⁶ whereas the 2011 study on PMFL did not report fluoroscopy data.³⁷

Complications

As for significant complications (see Table 2), it is worth noting that highly feared complications specifically related to MMVP (such as catheter entrapment or prosthesis damage) did not occur, whereas the studies only reported complications classically associated with LA ablations in general. Our pooled analysis found that these occurred in 10/179 (5.6%) MMVP patients and in 8/285 controls (2.8%), but while this entails a doubled complication rate, the difference did not reach statistical significance (p=0.28).³⁸ We note that in their 2005 study Lang and colleagues³⁴ reported as a complication the previously mentioned case that was aborted due to inability to cross the interatrial septum (thus bringing the total of cases to 27 for that analysis), but they otherwise excluded that case from further outcome analyses. For the sake of consistency, we decided to adhere to the authors' classification and consider the event as a complication, which is why we considered 179 cases instead of 178 only for complication analysis.

Populations, Techniques and Effectiveness

The overall population of 178 cases included 161 MMVP patients and 15 patients who did not have a MMVP (12 with a mitral annuloplasty ring³⁷ and 5 with a mechanical aortic valve prosthesis³⁵); separate data was not provided for these patients, so their data could not be singled out from pooled analysis. Aggregated results showed a trend towards increased atrial tachyarrhythmia recurrences in 64/178 cases versus 73/285 controls (36% versus 26%, p=0.053).³⁸

The 2005 single-center study by Lang and colleagues³⁴ enrolled 26

MMVP cases and 26 matched controls; it is not stated whether any of them had undergone catheter or surgical LA ablation procedures before. All underwent a now rather outdated circumferential PV ablation technique (aiming for PV potential abatement, without using a circular mapping catheter); most patients also received a mitral isthmus line and a posterior/roof line. After a 3-month blanking period and a mean of 10-month follow-up period (range: 1-12 months), the total AF and/or AT recurrence rate was high (50% versus 35%), despite extensive amiodarone use (given to all patients during the blanking period, then continued for an unspecified time only in patients who experienced recurrences). The difference in recurrence rates was not statistically significant when analyzing AF recurrences alone (27% versus 25%), but it did show a much higher incidence of post-ablation AT in MMVP patients than in controls (23% versus 2%, p=0.005). Total reablation rates also approached 50% in patients who experienced AT/AF recurrences (7/13 versus 7/14 patients). The current clinical applicability of these results is severely limited by very small populations, short and heterogeneous follow-up time, extensive amiodarone use, and an ablation technique that is no longer considered state-of-the-art.

The 2011 multi-center study by Lakkireddy and colleagues³⁵ enrolled 50 cases (41 with MMVP, 5 with mechanical aortic valve, 4 with both) and 50 matched controls; 4/50 cases (14%) had undergone surgical AF ablation at the time of valve surgery. All underwent PV antral isolation supported by intracardiac echocardiography, use of a circular mapping catheter and electroanatomic mapping; all patients with non-paroxysmal AF also underwent ablation of complex fractionated atrial electrograms and attempted epicardial ablation from within the coronary sinus. Further lesions were delivered in certain subpopulations, as detailed in the original paper (this included a mitral isthmus line in 20% of patients with valve prosthesis). After ablation, patients were followed up for 12 months, with antiarrhythmic drugs discontinued if patients were in sinus rhythm at the 2-month control. At 6 months, there was no significant difference in AF/AT recurrence rates off antiarrhythmic drugs (22% versus 16%, p=0.60); Table 2:

Significant complications in studies of left atrial ablation in patients with a mechanical mitral valve prosthesis

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Complications (cases vs controls)	Lang et al ³⁴ (Italy, 2005)	Hussein et al ³⁶ (USA, 2011)	Lakkireddy et al ³⁵ (USA, 2011)	Mountantonakis et al ³⁷ (USA, 2011)	Total
Procedure aborted due to inability to cross the interatrial septum	1/27 vs 0/26	-	-	-	1/179 vs 0/285
Transient ischemic attack	1/27 vs 0/26	-	-	-	1/179 vs 0/285
Femoral pseudoaneurysm	1/27 vs 0/26	1/81 vs 0/162	-	-	2/179 vs 0/285
Femoral arteriovenous fistula	-	-	2/50 vs 0/50	-	2/179 vs 0/285
Inguinal hematoma requiring intervention	-	1/81 vs 2/162	0/50 vs 1/50	-	1/179 vs 3/285
Bleeding requiring transfusion	-	1/81 vs 1/162	-	-	1/179 vs 1/285
Pericardial effusion / tamponade requiring drainage	-	0/81 vs 1/162	1/50 vs 1/50	-	1/179 vs 2/285
Diaphragmatic paralysis	-	-	1/50 vs 0/50	-	1/179 vs 0/285
Total	2/27 vs 0/52 (p=0.01)	3/81 vs 4/162 (p=0.52)	4/50 vs 2/50 (p=0.11)	0/21 vs 0/21	10/179 vs 8/285 (p=0.28)

there was still no significant difference off antiarrhythmic drugs at 12 months (20% versus 18%, p=0,60) after a mean of 1.3 and 1.2 procedures, considering that 17 cases and 10 controls had undergone repeat ablation.

The 2011 single-center study by Hussein and colleagues³⁶ is the largest to date, enrolling 81 MMVP cases (34.6% of them with a previous surgical LA ablation) and 162 matched controls (with no previous LA ablation). All underwent PV antral isolation supported by intracardiac echocardiography and a circular mapping catheter (without electroanatomical mapping) and ablation of superior vena cava potentials; some patients also underwent ablation of other non-PV triggers (44.4% of MMVP cases) and possibly also received other LA and RA ablation lines, as detailed in the original paper. Presenting arrhythmias and ablation maneuvers are described in much greater detail in this study compared to the other three. Unsurprisingly, MMVP patients with a previous surgical LA ablation had a greater likelihood of presenting with atypical flutter (67.9% versus 30.8%, p=0.0013). After a mean 24-month follow-up time (including a 2-month blanking period), the arrhythmia recurrence rate was higher in MMVP patients than in controls (49.4% versus 27.7%, p<0.001). Antiarrhythmic drugs were given in the blanking period and continued in some patients who had arrhythmia recurrences, but amiodarone was never used after ablation. The reablation rate was rather high in both patient groups (72.5% versus 73.3%), although MMVP cases required more ablations per person than controls (1.4±0.6 versus 1.2±0.5, p=0.003) and were less successful at last follow-up (69.1% versus 87.0%, p=0.0006). This study represents the largest, longest and most detailed study on LA ablations in MMVP patients so far, and the closest to clinical applicability in current practice.

Finally, the 2011 single-center study by Mountantonakis and colleagues on PMFL ablation37 enrolled just 21 cases (9 patients with MMVP and 12 with a mitral annuloplasty ring) and 21 matched controls. Of the 21 cases, 12 had undergone surgical AF ablation at the time of valve surgery, and 10 had undergone at least one catheter-based AF ablation after surgery (thus 14/21 patient had a mitral isthmus ablation performed in the past, in one way or the other, although in no patient the mitral isthmus was still blocked on reablation). The number of previous LA ablation was even higher

in controls compared to cases (2.1±1.2 versus 1.3±1.1, p=0.31). All underwent PV antral isolation and mitral isthmus line ablation (including epicardial ablation from the coronary sinus in some cases), supported by electroanatomical mapping and a circular mapping catheter; in patients with an excluded or ligated LA appendage, ablation at the stump site was also performed. In some cases, a steerable sheath was used to better manipulate the ablation catheter near the mitral valve. At a mean follow-up of just 6.1±3.5 months (including a 2-month blanking period), there was no significant difference in AF/PMFL freedom rate between cases and controls (71% versus 67%, with 57% and 71% respectively still on unspecified antiarrhythmic drugs). The authors report no data on repeat ablations. The extremely small and heterogeneous populations, high incidence of previous ablations, incomplete data on antiarrhythmic drug therapy, and extremely short follow-up time make the results of this study very difficult to translate into clinical practice.

State of the Art

Available data on LA ablations in MMVP patients prove that such procedures are feasible and relatively safe in high-volume centers, although they entail longer procedural and fluoroscopy times, a trend towards higher complication rates and worse arrhythmia-free survival.³⁸ However, these data come from case-control studies with relatively small populations, heterogeneous ablation techniques, and short follow-up time. They only reported arrhythmia-free survival, while failing to take arrhythmic burden and/or quality of life measures into consideration. Further studies are warranted to evaluate the long-term benefit of catheter ablation in patients with MMVP, as well as whether the reported results at short- and midterm are generalizable to less experienced operators and Institutions.

Other Cardiac Valve Devices

While most of the experience with intra-cardiac devices in LA ablations focuses on either septal closure devices or mechanical mitral valve prostheses, other possibilities should be taken into consideration. Two previously cited papers included a few patients with mechanical aortic valve prostheses and AF³⁵ or with a mitral annuloplasty ring and PMFL,³⁷ although no specific conclusions can be drawn on those subgroups. In 2012, Cheng and George also reported detection of dehiscence of a mitral annuloplasty ring on pre-ablation cardiac CT,³⁹ which prompted them to refrain from

using a circular mapping catheter during the procedure (as its shape would have conferred the greatest risk for entrapment). There are no published reports yet of LA ablation in patients equipped with a MitraClip (Abbott Vascular, Green Oaks, IL, USA), although need for such a procedure is likely to emerge.

Atrial Appendage Closure

Atrial fibrillation is the most frequent cause of ischemic stroke, particularly in the elderly,⁴⁰ and closure of the left atrial appendage (LAA), as the most likely site for thrombus formation, represents a promising approach to stroke risk reduction.41,42 Combining AF ablation with LAA closure holds particular appeal, as the two percutaneous procedures address different aspects of the same clinical condition. In 2012 Swaans and colleagues⁴³ reported a series of 30 patients who underwent combined LAA closure using the Watchman device (Boston Scientific/Atritech Inc, Plymouth, MN, USA) and AF ablation through PV isolation (using the purposebuilt PVAC catheter from Medtronic/Ablation Frontiers Inc, Carslbad, CA, USA), in addition to ablation of complex fractionated atrial electrograms in patients with long-standing persistent AF. The combined procedure was performed on warfarin, under general anesthesia, with fluoroscopic guidance and continuous transesophageal echocardiographic monitoring. The median total procedural time was 97.3 minutes (25th-75th percentile range: 75-115 minutes); LAA ablation accounted for a median of 38 minutes (25th-75th percentile range: 30-51 minutes) and required a median of 1.5 devices (25th-75th percentile range: 1-2 devices). There were only 3 minor periprocedural complications (minor bleedings) and no major complications. Post-ablation echocardiography and follow-up transesophageal echocardiography at 60 days confirmed successful LAA closure, although in one patient the Watchman device subsequently embolized to the abdominal aorta (without symptoms). The strategy for post-ablation AF recurrence detection in this study was particularly disappointing, consisting solely of repeated 12-lead ECGs (without Holter ECG monitoring). Still, after a blanking period of 3 months, at a 12-month follow-up 21/30 (70.0%) patients had no documented AF recurrence, while of the remaining 9/30 (30.0%) who experienced AF recurrences, 4 underwent repeat AF ablation with neither periprocedural complications nor any interference from the LAA closure device. This study proves the feasibility and relative safety of combined AF ablation and LAA closure, and suggest the same for repeat AF ablation in patients who already have a LAA closure device. It is worth remembering that in a substantial proportion of patients with AF (especially nonparoxysmal AF), the LAA appendage may represent an important trigger site requiring electrical isolation with ablation,⁴⁴ but there is no evidence on whether the presence of an endocardial LAA closure device may impede such an approach. Furthermore, the increasing availability of epicardial percutaneous LAA ligation devices⁴⁵ might be helpful to achieve both LAA isolation and closure in a single procedure.

Conclusions:

With the growing epidemic of AF, catheter ablation techniques will need to step up to meet the needs of a wider, more complicated population, including patients in whom previous surgical or percutaneous interventions left intra-cardiac devices in place. The current published experience on this regard is largely limited, but it suggests that such patients may safely undergo AF ablation in high-volume tertiary referral centers, and invites further studies on this matter.

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Journal Review

150 Journal of Atrial Fibrillation

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151 Journal of Atrial Fibrillation

Beheiry S, Themistoclakis S, Bonso A, Rossillo A, Corrado A, Raviele A, Al-Ahmad A, Wang P, Cummings JE, Schweikert RA, Pelargonio G, Dello Russo A, Casella M, Santarelli P, Lewis WR, Natale A. Left atrial appendage: An underrecognized trigger site of atrial fibrillation. Circulation. 2010;122:109-118

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