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Direct Current Cardioversion of Atrial Fibrillation in Patients With Left Atrial Appendage Occlusion Devices

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ABSTRACT

BACKGROUND Direct current cardioversion (DCCV) is a common rhythm control strategy in patients with symptomatic atrial fibrillation or flutter. There is no long-term data regarding the safety of DCCV in patients with endocardial left atrial appendage occlusion (LAAO) devices.

OBJECTIVES The purpose of this study was to assess the feasibility and safety of DCCV in patients with an LAAO device.

METHODS This multicenter retrospective study included 148 patients with an LAAO device who underwent DCCV for symptomatic atrial fibrillation or atrial flutter.

RESULTS The average age of the included patients was 72 ± 7 years and 59% were men. All patients (100%) had a transesophageal echocardiogram prior to DCCV. Device-related thrombus was seen in 2.7%. They were all successfully treated with oral anticoagulation (OAC) and were able to undergo DCCV after 6 to 8 weeks. DCCV restored sinus rhythm in all patients. None of the patients had DCCV-related thromboembolic complications. A total of 22% of patients were newly started on OAC after DCCV. There was no difference in DCCV-related complications between patients treated with or without OAC post-DCCV. Patients receiving OAC post-DCCV were found to undergo cardioversion at an earlier time after implantation (3.6 months [interquartile range (IQR): 0.7 to 8.6 months] vs. 8.6 months [IQR: 2.5 to 13.3 months]; $p = 0.003$). Three transient ischemic attacks, unrelated to DCCV, were found during follow-up. During a median follow-up of 12.8 months (IQR: 11.8 to 14.2 months), no device or left atrial thrombosis, device dislodgement, or a new device leak were observed. One patient died during follow-up due to noncardiac cause.

CONCLUSIONS DCCV is feasible in high-risk AF patients with an LAAO device without the need for oral anticoagulation if pre-procedural transesophageal echocardiography shows good device position, absence of device-related thrombus, and peridevice leak of ≤5 mm. The preliminary results are encouraging, but further large studies are warranted to establish safety. (J Am Coll Cardiol 2019;74:2267–74) © 2019 Published by Elsevier on behalf of the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

AF = atrial fibrillation

AFL = atrial flutter

DCCV = direct current cardioversion

DOAC = direct oral anticoagulants

LAAO = left atrial appendage occlusion

OAC = oral anticoagulants

TEE = transesophageal echocardiography

Direct current cardioversion (DCCV), a common rhythm control strategy for symptomatic atrial fibrillation (AF)/atrial flutter (AFL) patients, is associated with a small but substantial risk of stroke and systemic thromboembolism (1–3). The pivotal randomized trials of adjusted-dose warfarin versus direct oral anticoagulants (DOACs) demonstrated that the 30-day risk of stroke and systemic embolism after DCCV ranges between 0.3% to 1% (4–7). In the absence of anticoagulation, the risk of thromboembolic complications during the first 30 days post-cardioversion is amplified by >2-fold. A large Danish retrospective study that assessed around 16,000 patients showed significantly increased risk of systemic thromboembolism in the first 30 days after cardioversion in patients without anticoagulation (hazard ratio: 2.47; 95% confidence interval: 1.49 to 4.27) (8). Current guidelines from the United States, Canada, and Europe recommend use of anticoagulation starting 3 weeks prior to DCCV and continued use for at least 4 weeks post-procedure in the absence of strong contraindications (9–11).

Percutaneous left atrial appendage occlusion (LAAO) has emerged as an alternative for prevention of systemic embolization in AF patients who are not candidates for long-term oral anticoagulation (OAC). In such patients who have undergone LAAO, there is no long-term data regarding the feasibility and safety of DCCV post-LAAO in the absence of anticoagulation.

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METHODS

This is a retrospective, multicenter study involving consecutive AF patients with a Watchman LAAO device (Boston Scientific, Marlborough, Massachusetts) who underwent elective DCCV between July 2013 and July 2017 for the management of symptomatic AF/AFL. We included all patients age ≥18 years, with electrocardiogram results with AF or AFL, with symptoms attributed to AF/AFL, and who were able and willing to provide informed consent. We excluded patients who received chemical cardioversion, who had emergent DCCV due to hemodynamic instability (systolic blood pressure <90 mm Hg and heart rate >170 beats/min), and who were undergoing other invasive cardiac procedures. Baseline and procedural characteristics, anticoagulation management, and complications were retrieved from electronic medical records and analyzed. Clinical outcomes included safety and feasibility of performing DCCV post-LAAO implantation.

ANTITHROMBOTIC REGIMEN POST–LAAO IMPLANTATION. All patients received a standard post-Watchman antithrombotic regimen including 6 weeks of aspirin 81 mg daily + warfarin (International normalized ratio goal 2 to 3)/DOAC. Patients were changed to 6 weeks of aspirin 81 mg daily + clopidogrel 75 mg daily after surveillance transesophageal echocardiography (TEE) or cardiac computed tomography (CT) showed satisfactory device position, no device-related thrombus (DRT) or peridevice leak ≤5 mm. Subsequently, patients were changed to aspirin 81 mg daily alone at 6 months follow-up after another TEE or cardiac CT according to the manufacturer's recommendations (12).

DIRECT CURRENT CARDIOVERSION. Irrespective of any prior surveillance imaging, patients underwent another TEE just prior to DCCV for evaluation of the LAAO device apposition, DRT, and peridevice leak. In those patients with concern for device apposition, thrombus, or peridevice leak ≥5 mm, DCCV was not performed and patients were treated with OAC (warfarin/DOAC) with another follow up TEE at 4 to 6 weeks. Cardioversion was again attempted after the repeat TEE showed thrombus resolution and peridevice leak <5 mm.

DCCV was performed using synchronous electrical biphasic current (50 to 360 J) under conscious sedation. Post-DCCV antithrombotic regimen was prescribed at the discretion of the attending physician.

DEFINITIONS.

- *Acute procedural success*: restoration of normal sinus rhythm immediately after DCCV.
- *DCCV-related thromboembolic complications*: Definite or probable thromboembolic event within 6 weeks after index cardioversion. Definite thromboembolic event was defined as a stroke documented clinically and confirmed by CT or magnetic resonance imaging to be caused by cerebral infarction or a systemic embolism confirmed by imaging, surgery, or autopsy. Probable embolic complications included transient ischemic attacks (TIAs) that were not confirmed by imaging but suspected clinically by a neurologist.
- *DCCV-unrelated thromboembolic complications*: Definite or probable thromboembolic event after 6 weeks of cardioversion.
- *Major or minor bleeding*: Bleeding was defined according to the Bleeding Academic Research Consortium (13). Bleeding that is fatal or associated with hemoglobin drop of >3 g/dl, requirement of packed red blood cell transfusions, or intracranial hemorrhage was defined as major. Minor bleeding was any other bleeding that is not actionable or is

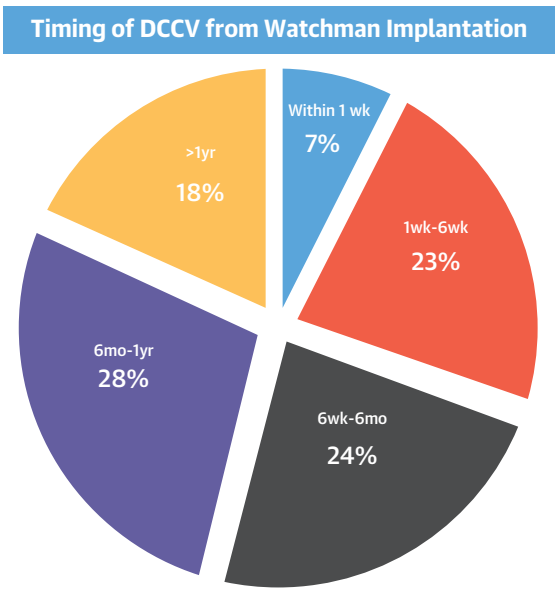
TABLE 1 Baseline Characteristics of the Patients (N = 148)

Age, yrs	72 ± 7
Male	59
Race	
Caucasian	80
African American	14
Hispanic	4
Asian	2
Atrial fibrillation type	
Paroxysmal	49
Persistent	44
Long-standing persistent	7
CHA_2DS_2-VASc score	3.8 ± 1.7
HAS-BLED score	3.4 ± 1.6
Hypertension	91
Diabetes	20
History of previous myocardial infarction	23
History of coronary artery bypass graft	18
Cardiomyopathy	27
Ischemic	18
Nonischemic	9
Obstructive sleep apnea	29
COPD	26
History of TIA/CVA	39
History of gastrointestinal bleed	39
Chronic renal insufficiency	28
Pacemaker or defibrillator implant	58
Class I antiarrhythmics	0
Class III antiarrhythmics	38
Amiodarone	10
Dofetilide	24
Dronedarone	4
Beta-blocker use	89
Calcium-channel blocker use	17
History of AF ablation	40
Mitral regurgitation	77
Trace	33
Mild	24
Moderate	13
Severe	7
Aortic regurgitation	34
Trace	21
Mild	9
Moderate	4
Left atrial size, mm	4.2 ± 0.5
Left ventricular ejection fraction, %	55 ± 9
Left ventricular end-systolic volume, mm	3.1 ± 0.8
Left ventricular end-diastolic diameter, mm	4.5 ± 0.8

Values are mean ± SD or %.

AF = atrial fibrillation; CHA_2DS_2-VASc = congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, prior stroke, transient ischemic attack, or thromboembolism, vascular disease, age 65–74 years, sex category (female); COPD = chronic obstructive pulmonary disease; CVA = cerebrovascular accident; HAS-BLED = hypertension, abnormal renal or liver function, stroke, bleeding, labile international normalized ratio, elderly, drugs or alcohol; TIA = transient ischemic attack.

FIGURE 1 Timing of DCCV From Watchman Procedure



The figure demonstrates the proportion of patients who had direct current cardioversion (DCCV) during different time frames from Watchman implantation.

actionable requiring medical intervention, but not meeting the criteria of major bleeding.

STATISTICAL ANALYSIS. Continuous variables were expressed as mean ± SD or median (interquartile range). Categorical variables were expressed as number (%). Continuous variables were compared using 2-sided unpaired Student's *t*-test or Wilcoxon rank sum test, as appropriate. Fisher exact test was used to compare categorical variables. All statistical analyses were performed using the STATA 14.2 (College Station, Texas). A p value ≤0.05 was considered statistically significant.

RESULTS

CLINICAL CHARACTERISTICS. We enrolled a total of 148 patients from the study period. The mean age was 72 ± 7 years, and 59% patients were male. The majority were Caucasian (80%) and had paroxysmal AF (49%). About 40% of patients had a prior AF ablation and 38% were treated with Class III antiarrhythmic drugs prior to cardioversion. Mean CHA_2DS_2-VASC and HAS-BLED scores of the patients were 3.8 ± 1.7

TABLE 2 Device-Related Thrombus

	Timing From LAAO Implantation	Anticoagulation Prior to DCCV	Treated With	Repeat TEE	DCCV	Post-DCCV OAC
Patient #1	3 months	Aspirin and clopidogrel	Apixaban × 8 weeks	Resolution	Success	Apixaban × 12 weeks
Patient #2	8.5 months	Aspirin only	Apixaban × 4 weeks	Resolution	Success	Apixaban × 12 weeks
Patient #3	11 months	Aspirin only	Rivaroxaban × 24 weeks	Resolution	Success	Rivaroxaban × 6 weeks
Patient #4	14 months	Aspirin only	Apixaban × 4 weeks	Resolution	Success	Apixaban × 6 weeks

DCCV = direct current cardioversion; LAAO = left atrial appendage occlusion; OAC = oral anticoagulants; TEE = transesophageal echocardiography.

and 3.4 ± 1.6, respectively. Other baseline characteristics of the included patients are shown in Table 1.

TIMING OF CARDIOVERSION. The majority of the DCCV (52%) were performed between 6 weeks to 1 year post-LAAO procedure. The median duration of DCCV post-procedure was 5.1 months (1 to 10.5 months). Figure 1 shows the details on the timing of DCCV from LAAO procedure.

TRANSESOPHAGEAL ECHOCARDIOGRAPHY PRIOR TO CARDIOVERSION. All patients underwent TEE under moderate sedation prior to cardioversion (100%). TEE detected device-related thrombus (DRT) in 2.7% (4 of 148) patients. All 4 patients were treated with a DOAC and subsequently underwent DCCV after documenting resolution of DRT on repeat imaging (Table 2). None of the patients had a peridevice leak of ≥5 mm, incomplete device apposition, or embolization.

ACUTE PROCEDURAL SUCCESS. DCCV successfully restored sinus rhythm in all patients.

ANTITHROMBOTIC REGIMEN POST-CARDIOVERSION. Table 3 summarizes the detailed characteristics of patients who were treated with and without OAC post-cardioversion. At the time of cardioversion 34% (51 of 148) were on OAC, 30% (44 of 148) dual antiplatelet therapy (aspirin 81 mg daily and clopidogrel 75 mg daily), and 36% (53 of 148) on single antiplatelet therapy (aspirin 81 mg daily). Immediately after DCCV, 22% (32 of 148) were newly started on OAC. The median duration of OAC post-cardioversion was 12 weeks (12 to 12 weeks). Patients treated with OAC post-DCCV underwent DCCV at an earlier time post-procedure compared with those not treated with OAC (3.6 months [0.7 to 8.6 months] vs. 8.6 months [2.5 to 13.3 months]; p = 0.003).

DCCV-RELATED THROMBOEMBOLIC COMPLICATIONS. None of the patients developed DCCV-related thromboembolic complications.

THROMBOEMBOLISM NOT RELATED TO DCCV. There were 3 TIAs that occurred after 3.5 months (3 to 4 months) of DCCV. In these patients, DCCV was performed after 13 months (9 to 13 months) of implantation. All 3 patients were in sinus rhythm when TIA occurred. There was no significant difference in age (69 ± 6.2 years vs. 72 ± 7.4 years; p = 0.4), CHA_2 DS_2-VASC (3 ± 1 vs. 3.8 ± 1.7; p = 0.3), and HAS-BLED (4.3 ± 0.6 vs. 3.4 ± 1.6; p = 0.3) scores between those who experienced a TIA versus those who did not. All patients were on aspirin 81 mg only during DCCV. None of them had evidence of thrombus or peridevice leak ≥5 mm on TEE. None of the patients with TIA received post-DCCV OAC. Detailed patient information with TIA is elucidated in Table 4.

TABLE 3 Comparison of Patients Treated With and Without Post-DCCV OAC

	OAC Post-DCCV (n = 83)	No OAC Post-DCCV (n = 65)	p Value
Age, yrs	72 ± 7.8	72 ± 7.1	0.7
Male	64	52	0.1
Race			
Caucasian	76	86	0.2
African American	16	11	
Hispanic	5	3	
Asian	3	0	
CHA_2DS_2-VASc score	3.9 ± 2	3.8 ± 1.4	0.6
Left ventricular ejection fraction, %	54 ± 9	54 ± 8.8	0.8
Coronary artery disease	64	48	0.04
Diabetes	19	20	0.9
Hypertension	92	89	0.6
Prior TIA/CVA	40	38	0.8
Prior GI bleeding	35	44	0.1
AF type			
Paroxysmal	55	40	0.09
Persistent	36	54	
Permanent	9	6	
Timing of DCCV from Watchman, months	3.6 (0.7-8.6)	8.6 (2.5-13.3)	0.003
Probable thromboembolic event not related to DCCV	0 (0.0)	3 (4.6)	0.04
Bleeding events post-DCCV	5 (6.2)	1 (1.4)	0.1
Major	4 (5.0)	0 (0.0)	0.07
Minor	1 (1.2)	1 (1.4)	0.8

Values are mean ± SD, %, median (interquartile range), or n (%).
GI = gastrointestinal; other abbreviations as in Tables 1 and 2.

TABLE 4 Patients With TIA

Patient	Age/Sex	AF Type	Event From DCCV, Months	DCCV Timing From LAAO, Months	OAC/APT Before DCCV	TEE Before DCCV	Post-DCCV Anticoagulation	DRT	Peridevice Leak ≥5 mm	Follow-Up
TIA 1	76/M	Paroxysmal	3	9	Aspirin	Yes	No	No	No	Continued on aspirin 81 mg daily
TIA 2	64/M	Paroxysmal	3.5	13	Aspirin	Yes	No	No	No	Continued on aspirin 81 mg daily
TIA 3	67/M	Persistent	4	13	Aspirin	Yes	No	No	No	Aspirin changed to clopidogrel 75 mg daily

AF = atrial fibrillation; APT = antiplatelet therapy; other abbreviations as in Tables 1 and 2.

BLEEDING COMPLICATIONS. Bleeding events occurred in 4% (6 of 148) of patients of which 4 were major and 2 were minor. More bleeding events occurred in patients treated with post-DCCV OAC, but this was not statistically significant (6% vs. 1.5%; p = 0.20). All major bleeding occurred in post-DCCV OAC group (4.6% vs. 0%; p = 0.07). In major bleeding, group 3 had GI bleeding requiring transfusion while 1 had intracranial hemorrhage. There was no major difference in age between patients who had bleeding versus those who did not (69 ± 7 years vs. 72 ± 7 years; p = 0.10). No difference in CHA_2 DS_2-VASC score (3.6 ± 1.6 vs. 3.8 ± 1.7; p = 0.70) and HAS-BLED (3.8 ± 0.7 vs. 3.4 ± 1.6; p = 0.30) scores were noted between patients with and without bleeding events. Other characteristics of patients with bleeding complications are outlined in Table 5.

OTHER OUTCOMES. During a median follow up of 12.8 months (11.8 to 14.2 months) after DCCV, 0 device or LA thrombus, 0 device dislodgments or new device leaks, and 1 noncardiovascular mortality (due to malignancy) were observed.

DISCUSSION

Our study demonstrates the feasibility of DCCV in high-risk AF patients who underwent Watchman percutaneous LAAO in the absence of anticoagulation (Central Illustration). The updated American Heart Association/American College of Cardiology/Heart Rhythm Society guidelines recommend anticoagulation for at least 3 weeks before and 4 weeks after cardioversion in patients with AF of >48 h or unknown duration and suggests that it is reasonable to proceed with cardioversion without preceding anticoagulation use if no left atrial appendage (LAA) thrombus is identified by TEE and anticoagulation is maintained after cardioversion for at least 4 weeks (11). There are no existing guidelines regarding DCCV in patients with endocardial LAAO devices. Currently, periprocedural TEE and OAC use after DCCV is at the discretion of the operator. While further prospective study comparing DCCV with or without TEE and OAC might be required to fully answer this question, we demonstrated that if pre-procedural TEE shows good device position, lack of DRT, and a peridevice leak of <5 mm, it is feasible to perform DCCV without OAC.

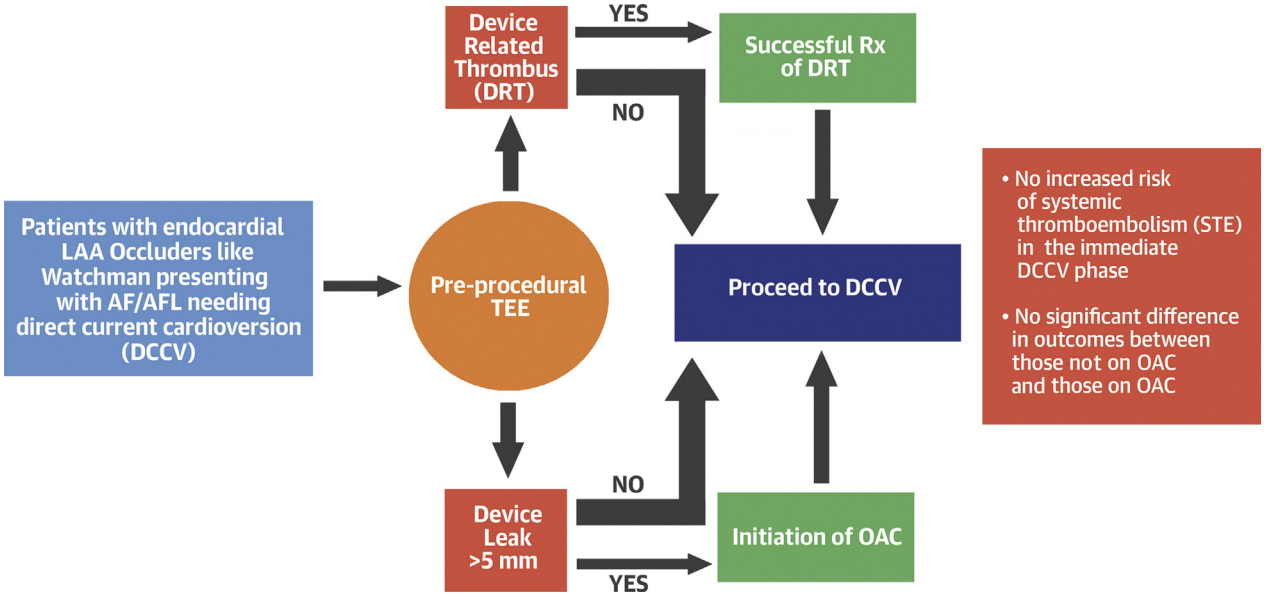
The role of TEE-guided DCCV has been defined in previous cardioversion anticoagulation studies (4,6). In patients with endocardial LAAO devices, pre-procedural TEE can potentially guide DCCV in 2 ways. First, it can detect DRT and alter the management. TEE changed management in 4 patients (2.7%) who were diagnosed with DRT in our study. They were successfully anticoagulated leading to thrombus resolution, and underwent successful DCCV later. The DRT rate in our study is lower than recently reported (3.7%) from an analysis of 4 major trials and registry

TABLE 5 Bleeding Complications

	Sites of Bleeding	Timing From Watchman Placement	Indication for Watchman	Anticoagulation Prior to DCCV	Peridevice Leak	Device-Related Thrombosis	Post-DCCV OAC
Major bleeding							
Patient #1	GI bleeding requiring transfusion	5 weeks	History of fall and at risk of bleeding	Rivaroxaban	No	No	Rivaroxaban × 6 weeks
Patient #2	GI bleeding requiring transfusion	3 months	History of bleeding	Aspirin + clopidogrel	No	No	Apixaban × 6 weeks
Patient #3	GI bleeding requiring transfusion	2.5 months	History of bleeding	Aspirin + clopidogrel	No	No	Apixaban × 6 weeks
Patient #4	Intracranial hemorrhage	8 months	History of bleeding	Aspirin	4-mm leak	No	Rivaroxaban × 6 weeks
Minor bleeding							
Patient #1	GI bleeding	15 months	History of bleeding	Aspirin	No	No	No
Patient #2	GU bleeding	14 months	History of bleeding	Aspirin	No	Yes	Warfarin × 6 weeks

GU = genitourinary; other abbreviations as in Tables 2 and 3.

CENTRAL ILLUSTRATION **Direct Current Cardioversion in Patients With Left Atrial Appendage Occlusion Devices**



Sharma, S.P. et al. J Am Coll Cardiol. 2019;74(18):2267–74.

This figure shows that patients with the Watchman device can safely proceed to DCCV if pre-procedural TEE is negative for device related thrombus or >5 mm device leak. In patients with DRT, DCCV was feasible after resolution of thrombus. In patients with >5 mm device leak, DCCV was successfully performed after initiation of OAC. AF = atrial fibrillation; AFL = atrial flutter; LAA = left atrial appendage; OAC = oral anticoagulants; TEE = transesophageal echocardiography.

studies on the LAAO device (14). Consistent with prior study from real-life experience (15), DRT occurred both early and late after LAAO in our study. Second, TEE can help in the management by identifying peridevice leak. The PROTECT-AF (Percutaneous Closure of the Left Atrial Appendage Versus Warfarin Therapy for Prevention of Stroke in Patients With Atrial Fibrillation) substudy showed that residual leak into LAA after percutaneous closure with the device is common, with 32% at 12 months (16). Although the study did not find any association between residual peridevice flow and composite of stroke, systemic embolism, and cardiovascular death, the authors have cautioned to take the result as hypothesis-generating rather than confirmatory because of the low event rate and limited power. Hanazawa et al. (17) reported a case of stroke on the second day after DCCV in a patient with the LAAO device (implanted 15 months before DCCV), who had evidence of TEE detected narrow residual flow and had received post-DCCV aspirin only. There is no other literature on the risk of DCCV-related thromboembolic complications in patients with peridevice leak. However, data from DCCV after surgical LAA closure showed a strong association between residual communication and thrombosis risk (18). The clinical implications of residual flow after endocardial LAAO in patients undergoing DCCV needs to be further studied.

To our knowledge, there is only 1 published report on DCCV in patients with LAAO devices. From the long-term follow-up of patients with LAAO from a single-center registry, Berte et al. (19) reported the outcomes of post-closure DCCV in a small cohort as a substudy. In the substudy, all of the DCCVs (26 patients, 41 DCCVs) were done after >1 year post-LAAO procedure, of which 41% of DCCVs (17 of 41) were done without therapeutic anticoagulation and TEE. Similar to our result, Berte et al. (19) also did not find any DCCV-related complications. The main strengths of our study are larger multicenter experience and inclusion of DCCV at various timeframes after implantation.

A total of 3 (2%) TIAs occurred >3 months after cardioversion in our study. Their workups with magnetic resonance imaging and TEE were negative. Mechanistically, risk of post-cardioversion thromboembolism is related to transient atrial mechanical dysfunction seen after restoration of normal sinus rhythm termed “atrial stunning” (20). Abnormal blood flow patterns caused by atrial stunning have been associated with increased risk of thromboembolism. Left atrial stunning lasts a few weeks, being at its maximum immediately after cardioversion with

progressive improvement of atrial function thereafter (21), with a complete resolution within a few minutes to 4 to 6 weeks depending on the duration of the preceding atrial fibrillation, atrial size, and structural heart disease (20). Because of this reason, it seems reasonable to say that TIA in our cohort was not related to DCCV. The cause of TIA in these patients could be most likely due to small vessel disease given the presence of other risk factors such as diabetes, hypertension, and CHF. Hence, they were appropriately treated using single or dual antiplatelet therapy.

Post-DCCV OAC led to increased bleeding events. Bleeding rate in the post-DCCV OAC group represents higher than reported in other studies in patients with AF without LAAO (4,22,23). This is in keeping with the fact that >90% of patients had either history of bleeding or were at increased risk of bleeding in the LAAO group.

STUDY LIMITATIONS. The main limitation of our study is its retrospective nature. Selection bias of patients undergoing DCCV could not be ruled out. As there was no control group, we could not totally discount the beneficial effect of post-DCCV OAC, because 22% of our cohort was newly started on OAC after cardioversion. However, those patients are at increased risk of major bleeding and received a Watchman LAAO device in the first place due to intolerance to long-term OAC. Our result is limited to the Watchman device; extrapolation of this result to other endocardial LAAO devices should be done with caution. Furthermore, whether these results would apply to those undergoing preprocedural cardiac CT instead of TEE is not known.

CONCLUSIONS

DCCV is feasible in high-risk AF patients with an LAAO device without the need for oral anticoagulation if pre-procedural TEE shows good device position, absence of DRT, and peridevice leak ≤5 mm. Our study shows promising safety results with no DCCV-related thromboembolic complications, albeit in a small cohort of patients. These preliminary results are encouraging, but further large studies are warranted to establish safety. The true incidence of DCCV-related thromboembolic complications can only be assessed in larger population. The zero event rate in our small cohort of patients could be solely due to lower sample size. A larger sample with adequate outcome events is also necessary to yield the unbiased predictors of DCCV-related complications in patients with Watchman device.

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PERSPECTIVES

COMPETENCY IN PATIENT CARE AND PROCEDURAL SKILLS: In patients who have undergone LAAO with a Watchman device, DCCV can be safely performed without anticoagulation after TEE excludes device-related thrombus or other contraindications.

TRANSLATIONAL OUTLOOK: Further studies are needed to determine if cardioversion can be performed without TEE after LAAO in patients with atrial fibrillation who are not anticoagulated.

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