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Risk Factors of Complications in Patients With Persistent or Long-Standing Persistent Atrial Fibrillation/Atrial Flutter Who Underwent Electrical Cardioversion: A Multicenter Cardioversion Registry

Ki-Hun Kim [1*] **Junbeom Park** [2*] **Donghwan Ku** [1] **Jino Park** [1] **Seunghwan Kim** [1] **Dong-Kie Kim** [1] **Doo-Il Kim** [1] **Sun Gyu Choi** [3] **Pil-Sung Yang** [4] **Ju Youn Kim** [5] **Jaemin Shim** [6] **Jinhee Ahn** [7] **Sung Ho Lee** [8] **Sung Il Im** [9] **and Hong Euy Lim** [10]

[1]Division of Cardiology, Department of Internal Medicine, Haeundae Paik Hospital, Inje University College of Medicine, Busan, Korea
[2]Division of Cardiology, Department of Internal Medicine, Ewha Womans University College of Medicine, Seoul, Korea
[3]Medical Research Institute, Haeundae Paik Hospital, Inje University College of Medicine, Busan, Korea
[4]Division of Cardiology, Department of Internal Medicine, CHA Bundang Medical Center, CHA University College of Medicine, Seoul, Korea
[5]Division of Cardiology, Department of Internal Medicine, Heart Vascular and Stroke Institute, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Korea
[6]Division of Cardiology, Department of Internal Medicine, Korea University Anam Hospital, Korea University College of Medicine, Seoul, Korea
[7]Division of Cardiology, Department of Internal Medicine, Busan National University Hospital, Busan University College of Medicine, Busan, Korea
[8]Division of Cardiology, Department of Internal Medicine, Kangbuk Samsung Hospital, Sungkyunkwan University College of Medicine, Seoul, Korea
[9]Division of Cardiology, Department of Internal Medicine, Kosin University Gospel Hospital, Kosin University College of Medicine, Busan, Korea
[10]Division of Cardiology, Department of Internal Medicine, Chung-Ang University Gwangmyeong Hospital, Chung-Ang University College of Medicine, Gwangmyeong, Korea

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Address for Correspondence:
Hong Euy Lim, MD
Division of Cardiology, Department of Internal Medicine, Chung-Ang University Gwangmyeong Hospital, Chung-Ang University College of Medicine, 110 Deokan-ro, Gwangmyeong 14353, Republic of Korea.
Email: hongeuy1046@gmail.com

*Ki-Hun Kim and Junbeom Park contributed equally to this work.

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ORCID iDs
Ki-Hun Kim
https://orcid.org/0000-0002-6599-6895
Junbeom Park
https://orcid.org/0000-0003-2192-9401
Donghwan Ku
https://orcid.org/0009-0005-4332-4915
Jino Park
https://orcid.org/0000-0002-3497-8782

ABSTRACT

Background: Identifying the risks related to the complications of electrical cardioversion (ECV) can alert the determinaton of rhythm control in patients with atrial fibrillation (AF).
Methods: We retrospectively reviewed 1,058 patients who underwent ECV for persistent or long-standing persistent AF/atrial flutter (AFL) from multiple centers. Patients were classified into the no-complication (1,023 patients) and complication (35 patients) groups based on the following major complications: stroke and/or systemic embolism (SSE), myocardial infarction, major bleeding, implantation of cardiac implantable electronic devices, ventricular tachycardia/fibrillation, and death at 1 year follow-up after ECV.
Results: Compared with the no-complication group, the complication group exhibited a higher proportion of female patients (37% vs. 22%), as well as a higher proportion of patients with older age (67 ± 11 vs. 61 ± 10 years), diabetes mellitus (DM) (49% vs. 24%), heart failure (HF) (49% vs. 30%), SSE (23% vs. 9%), high CHA_2DS_2-VASc (CV) score (3.6 ± 1.8 vs. 2.2 ± 1.4), low left ventricular ejection fraction (LVEF) (50 ± 16% vs. 58 ± 21%), and high

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Seunghwan Kim
https://orcid.org/0000-0002-2641-9606
Dong-Kie Kim
https://orcid.org/0000-0002-0268-5395
Doo-Il Kim
https://orcid.org/0000-0002-3453-0427
Sun Gyu Choi
https://orcid.org/0000-0003-2904-5862
Pil-Sung Yang
https://orcid.org/0000-0002-6552-1742
Ju Youn Kim
https://orcid.org/0009-0003-2452-4423
Jaemin Shim
https://orcid.org/0000-0001-8251-1522
Jinhee Ahn
https://orcid.org/0000-0001-6179-1254
Sung Ho Lee
https://orcid.org/0000-0002-1018-7871
Sung Il Im
https://orcid.org/0000-0003-2544-2422
Hong Euy Lim
https://orcid.org/0000-0001-8102-8352

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Disclosure

The authors have no potential conflicts of interest to disclose.

Author Contributions

Conceptualization: Kim KH. Data curation: Kim KH, Ku D, Park J,[1] Kim S, Kim DK, Kim DI, Yang PS, Kim JY, Shim JM, Ahn J, Lee SH, Im SI. Formal analysis: Choi SG. Writing - original draft: Kim KH, Park J.[2] Writing - review & editing: Lim HE.

Park J,[1] Jino Park; Park J;[2] Junbeom Park.

left atrial volume index (LAVI) (51 ± 26 vs. 40 ± 20 mL/m^2). Class I and III antiarrhythmics were less prescribed in the complication group than in the no-complication group (57% vs. 76%). Univariate analysis for complications revealed age (≥ 65 years), female sex, DM, HF, SSE, LVEF (< 50%), LAVI (≥ 40 mL/m^2), CV score (≥ 3), bradycardia on Holter (< 60/min), and no antiarrhythmics as risk factors. Among these, multivariate analysis revealed clinical significance of female sex and SSE.

Conclusion: Female sex and a history of SSE were the most important risk factors of complications in patients with persistent or long-standing persistent AF/AFL who underwent ECV.

Keywords: Atrial Fibrillation; Complication; Electrical Cardioversion

INTRODUCTION

Atrial fibrillation (AF) is the most frequent sustained arrhythmia, and its prevalence is continuously increasing worldwide. Therefore, the early identification and adequate management of AF are of clinical significance. AF management includes prevention of stroke, and rate or rhythm control.[1,2] As rhythm control can improve symptom scores and clinical outcomes including cardiovascular death, stroke, or hospitalization due to heart failure (HF), it has received increasing attention in patients with symptomatic paroxysmal AF or persistent AF with HF.[3,4] Accordingly guidelines suggest that AF ablation should be considered in symptomatic patients with AF and in those with AF and HF.[1,2]

However, the criteria for the selection of patients with persistent or long-standing persistent AF/atrial flutter (AFL) for rhythm control remain controversial.[5,6] Notably, guidelines do not provide a clear consensus on the management of persistent AF without HF.[2] In addition, the outcomes of rhythm control remain unsatisfactory, and sometimes serious complications related to the rhythm control, requiring the implantation of cardiac implantable electronic devices (CIEDs), may also occur.[5] Therefore, suitable patient selection and relatively economical and effective tools for rhythm control are clinically crucial for optimal rhythm control.[6,7] Electrical cardioversion (ECV) is an easy and effective method for the initial rhythm control of AF/AFL.[8] In addition, sinus rhythm (SR) is hardly maintained when ECV fails to achieve sinus conversion in persistent or long-persistent AF/AFL, which may guide the selection of rate control over rhythm control. However, ECV may cause thromboembolic and arrhythmic complications, particularly more frequently in patients with severe underlying heart disease.[9] Therefore, the identification of patients at a high risk of ECV could alert the determination of rhythm control, and a cautious approach could be employed for these patients.[10,11] Therefore, this study aimed to identify the clinical risk factors of complications in patients with persistent or long-standing persistent AF/AFL who underwent ECV.

METHODS

The preliminary study of this retrospective, nonrandomized multicenter study has been published previously.[5] We reviewed and selected patients, aged ≥ 20 years who underwent ECV for persistent or long-standing persistent AF/AFL. At least over 100 patients were encouraged for enrollment at each center. To avoid selection bias, we included all patients

for a specific time period within the range from 2010 to 2019 without any exclusion criteria. Notably, 1,058 patients from nine centers were selected. We excluded patients aged < 20 years, those who did not undergo baseline electrocardiography before ECV, those with insufficient follow-up medical records for at least 1 year after ECV, those who underwent catheter or surgical ablation for AF or AFL, and those who were implanted with a CIED; permanent pacemaker, implantable cardioverter defibrillator (ICD), or cardiac resynchronization therapy (CRT). Non-pharmacological rhythm control strategies after ECV were the option of the treating physicians.

The administration of antiarrhythmic medications before and after ECV was at the discretion of the treating physician. Anticoagulation therapy was administered according to the guidelines available at the time of enrollment. Notably, persistent or long-standing persistent AF/AFL was treated with warfarin with an international normalized ratio (2.0–3.0) or direct oral anticoagulants (DOACs) for at least 3 weeks before ECV, followed by at least 4 weeks of anticoagulation after ECV and continued thereafter depending on CHA_2DS_2-VASc (CV) score of the patient. ECV was preceded by transesophageal echocardiography whenever possible, and it was delayed if thrombi were detected. ECV was performed following complete thrombus resolution using anticoagulation therapy under sedation according to contemporary guidelines. Although the energy of the biphasic shock was at the discretion of the treating physician, mainly initial energy (200 J) of biphasic shock was chosen for the first shock and increased to maximum for subsequent shocks. If needed, amiodarone infusion was performed for subsequent shocks of failed ECV. External shocks were applied in either the anteroposterior or anterolateral electrode positions.[8]

Patients were classified into a no-complication (1,023 patients) and a complication (35 patients) groups based on the major complications, including the requirement of temporary or permanent pacemaker implantation for bradyarrhythmias, ICD or CRT implantation for serious ventricular arrhythmias or combined HF management, hospitalization for HF, major bleeding, stroke and/or systemic embolism (SSE), myocardial infarction (MI), sustained ventricular tachycardia/fibrillation (VT/VF), and cardiovascular or all-cause death during or after ECV at 1-year follow-up. Major bleeding was defined by the International Society of Thrombosis and Hemostasis, which were an acute and overt bleeding event with a decrease in hemoglobin of ≥ 2 g/dL, a transfusion of at least 2 units of packed red blood cells, or bleeding within a critical area or organ.[12] Diagnosis of HF was depending on the treating physician based on the patient's symptoms and signs due to a cardiac disorder, supported by elevated natriuretic peptide levels and/or objective findings of pulmonary or systemic vascular congestion, regardless of the left ventricular ejection fraction (LVEF). Bradycardia on the Holter was defined as average heart rate less than 60 beats/min in 24 hour. The cardiothoracic ratio was measured on the postero-anterior view of the chest radiograph, and the maximal horizontal cardiac and thoracic diameters were considered.

Statistical analysis

Continuous variables are expressed as the mean ± standard deviation. Data were compared using the pared Students' *t*-test. Categorical variables, are expressed as numbers and percentages, and were compared using χ^2 or Fisher's exact tests. Clinical risk factors for ECV complications were identified using the univariate and multivariate logistic models. Controlling variables included age (≥ 65 years), female sex, HF, diabetes mellitus (DM), SSE, LVEF (< 50%), Left atrial volume index (LAVI) (≥ 40 mL/m^2), CV score (≥ 3), bradycardia on Holter (< 60/min), and no use of antiarrhythmics. Odds ratios and 95% confidence intervals

(CIs) were computed to identify clinical risk factors. Two-tailed, $P < 0.05$ was considered statistically significant. All statistical analyses were conducted using the SPSS software (version 25.0; SPSS Inc., Chicago, IL, USA).

Ethics statement

This study was approved by the Institutional Review Board of Haeundae Paik Hospital (HPIRB No. 2021-10-022), and all patients provided written informed consent for ECV and management.

RESULTS

The mean age of patients was 61 ± 10 years, and of the 1,058 patients, 824 (78%) were males. Success rate of ECV for persistent or long-standing persistent AF/AFL was 92% (969 patients) and complication rate was not different between success and failed ECV group (29 [3.0%] vs. 6 [6.7%], $P = 0.053$). **Table 1** presents the list of complications during and after ECV for persistent or long-standing persistent AF/AFL during 1 year follow-up period. The number of occurrences of each complication is listed in **Supplementary Table 1**. Notably, 41 cases of complications (3.9%) occurred in 35 patients. CIEDs were implanted in 23 patients (2.1%; temporary pacemaker, permanent pacemaker, ICD and CRT in 2, 10, 6 and 5 patients, respectively). Three (0.3%) patients were admitted for aggravated HF, and embolism related complications (SSE and MI) and major bleeding occurred in five patients (0.5%), respectively. One patient with HF experienced MI. Furthermore, one patient with permanent pacemaker experienced VT/VF; the pacemaker was changed to an ICD. In total, three (0.3%) patients died; one due to sustained VT/VF after permanent pacemaker implantation, and others due to ST-elevation MI and cholangiocarcinoma.

Table 2 presents the baseline clinical characteristics of the study groups according to complications for persistent or long-standing persistent AF/AFL who underwent ECV. No-complication and complication groups included 1,023 and 35 patients, respectively. Compared with the no-complication group, the patients in the complication group were older (67 ± 11 vs. 61 ± 10 years, $P = 0.002$), and were mostly females (13 [37%] vs. 221 [22%], $P = 0.029$), with a higher proportion of patients with a history of DM (17 [49%] vs. 244 [24%], $P = 0.001$), HF (17 [49%] vs. 306 [30%], $P = 0.018$) and SSE (8 [23%] vs. 91 [9%], $P = 0.012$),

Table 1. Lists of complications after electrical cardioversion for persistent or long-standing persistent atrial fibrillation/atrial flutter observed during the 1 year follow-up

Complications	Cases (n = 35)
Temporary pacemaker implantation	2
Permanent pacemaker implantation	10
ICD implantation	6
CRT implantation	5
Hospitalization for heart failure	3
SSE	2
Myocardial infarction	3
Major bleeding	5
Sustained VT/VF	2
Cardiovascular death	2
Non-cardiovascular death	1
Total	41

ICD = implantable cardioverter defibrillator, CRT = cardiac resynchronization therapy, SSE = stroke and/or systemic embolism, VT = ventricular tachycardia, VF = ventricular fibrillation.

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and higher CV score (3.6 ± 1.8 vs. 2.2 ± 1.4, $P < 0.001$), lower LVEF (50 ± 16% vs. 58 ± 21%, $P = 0.021$), and higher LAVI (51 ± 26 vs. 40 ± 20 mL/m^2, $P = 0.018$). Mean duration of AF/AFL (complication group: 48.0 ± 42.5 months; no-complication group: 45.2 ± 39.3 months [$P = 0.683$]), form of AF/AFL, and duration of anticoagulation, as well as baseline medications, except flecainide and clopidogrel, did not differ significantly between the groups. Notably, flecainide was prescribed less frequently (1 [3%] vs. 173 [17%], $P = 0.020$) and clopidogrel was prescribed more frequently (4 [11%] vs 36 [4%], $P = 0.020$) in the complication group. Furthermore, total class I and III antiarrhythmics were less prescribed in the complication group (20 [57%] vs. 773 [76%], $P = 0.013$) (**Table 3**).

Univariate analysis revealed age (≥ 65 years) (hazard ratio [HR] 2.82 [95% CI, 1.40–5.66], $P = 0.004$), female sex (HR, 2.14; 95% CI, 1.06–4.33; $P = 0.033$), history of DM (HR, 3.02; 95% CI, 1.53–5.94; $P = 0.001$), history of HF (HR, 2.21; 95% CI, 1.13–4.35; $P = 0.021$), history of SSE (HR, 3.04; 95% CI, 1.34–6.88; $P = 0.008$), LVEF (< 50%) (HR, 3.08; 95% CI, 1.52–6.24; $P = 0.002$), LAVI (≥ 40mL/m^2) (HR, 2.35; 95% CI, 1.18–4.68; $P = 0.016$), CV score (≥ 3) (HR, 5.21; 95% CI, 2.41–11.23; $P < 0.001$), bradycardia on Holter (< 60/min) (HR, 3.25; 95% CI, 1.32–7.97; $P = 0.010$), and no antiarrhythmics (HR, 2.32; 95% CI, 1.17–4.60; $P = 0.016$) as clinical risk factors of complications in patients with persistent or long-standing

Table 2. Baseline clinical characteristics of the study groups according to complications in patients with persistent or long-standing persistent AF/AFL who underwent electrical cardioversion

Variables	No complication group (n = 1,023)	Complication group (n = 35)	*P* value
Age, yr	61 ± 10	67 ± 11	0.002
Females, %	221 (22)	13 (37)	0.029
Hypertension, %	664 (65)	24 (69)	0.655
Diabetes mellitus, %	244 (24)	17 (49)	0.001
Heart failure, %	306 (30)	17 (49)	0.018
SSE, %	91 (9)	8 (23)	0.012
PAD, %	7 (1)	0 (0)	1.000
MI, %	20 (2)	2 (6)	0.163
CAD, %	100 (10)	7 (20)	0.077
CV score	2.2 ± 1.4	3.6 ± 1.8	< 0.001
Hyperthyroidism, %	48 (5)	1 (3)	1.000
LVEF, %	58 ± 21	50 ± 16	0.021
LA diameter, mm	46 ± 6	47 ± 10	0.554
LA volume index, mL/m^2	40 ± 20	51 ± 26	0.018
LV mass index, g/m^2	90 ± 26	97 ± 29	0.214
TEE, %	554 (54)	19 (54)	0.998
HR on Holter, /min	74 ± 16	69 ± 21	0.149
Cardiac size, mm	155 ± 18	160 ± 23	0.194
Thoracic size, mm	303 ± 26	300 ± 20	0.580
Cardiothoracic ratio	0.51 ± 0.06	0.53 ± 0.06	0.166
Form of AF or AFL			0.438
AF, %	925 (90)	32 (91)	
AFL, %	61 (6)	3 (9)	
AF and AFL (mixed), %	37 (4)	0 (0)	
Duration of AF/AFL, mon	45.2 ± 39.3	48.0 ± 42.5	0.683
Duration of anticoagulation			0.271
≥ 2 mon	866 (85)	32 (91)	
Under 2 mon	136 (13)	2 (6)	
None	21 (2)	1 (3)	

Values are presented as number (%) or mean ± standard deviation.
Cardiac and thoracic size was measured using maximal horizontal cardiac and thoracic diameters on the postero-anterior view of the chest radiograph, respectively.
AF = atrial fibrillation, AFL = atrial flutter, SSE = stroke and/or systemic embolism, PAD = peripheral artery disease, MI = myocardial infarction, CAD = coronary artery disease, CV = CHA_2DS_2-VASc, LVEF = Left ventricular ejection fraction, LA = left atrium, LV = left ventricle, TEE = trans-esophageal echocardiography, HR = heart rate.

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Table 3. Baseline medications of the study groups at enrollment according to complications in patients with persistent or long-standing persistent atrial fibrillation/atrial flutter who underwent electrical cardioversion

Variables	No complication group (n = 1,023)	Complication group (n = 35)	*P* value
ACEI/ARB, %	379 (37)	18 (51)	0.085
Beta blocker, %	514 (50)	20 (57)	0.422
Digoxin, %	30 (3)	1 (3)	1.000
Diltiazem, %	77 (8)	4 (11)	0.336
Verapamil, %	33 (3)	0 (0)	0.623
Amiodarone, %	324 (32)	14 (40)	0.299
Dronedarone, %	14 (1)	0 (0)	1.000
Flecainide, %	173 (17)	1 (3)	0.020
Pilsicainide, %	45 (4)	1 (3)	1.000
Propafenone, %	209 (20)	3 (9)	0.089
Sotalol, %	16 (2)	1 (3)	0.438
Total (class I + III) antiarrhythmics, %	773 (76)	20 (57)	0.013
DOACs, %	766 (75)	24 (69)	0.399
Warfarin, %	207 (20)	7 (20)	1.000
Heparin, %	385 (38)	16 (46)	0.333
Low molecular weight heparin, %	2 (0)	0 (0)	1.000
Aspirin, %	56 (6)	3 (9)	0.439
Clopidogrel, %	36 (4)	4 (11)	0.039

Values represent number (%).
ACEI = angiotensin-converting enzyme inhibitor, ARB = angiotensin receptor blocker, DOAC = direct oral anticoagulant.

Table 4. Univariate and multivariate analysis of risk factors of complications in patients with persistent or long-standing persistent atrial fibrillation/atrial flutter who underwent electrical cardioversion

Variables	Univariate analysis		Multivariate analysis	
	Hazard ratio (95% CI)	*P* value	Hazard ratio (95% CI)	*P* value
Age, ≥ 65 yr	2.82 (1.40–5.66)	0.004	0.85 (0.28–2.53)	0.764
Female	2.14 (1.06–4.33)	0.033	3.99 (1.31–12.18)	0.015
Diabetes mellitus	3.02 (1.53–5.94)	0.001	2.22 (0.75–6.55)	0.150
Heart failure	2.21 (1.13–4.35)	0.021	1.33 (0.45–3.95)	0.603
SSE	3.04 (1.34–6.88)	< 0.001	3.62 (1.17–11.18)	0.026
LVEF, < 50%	3.08 (1.52–6.24)	0.002	2.34 (0.73–7.48)	0.152
LA volume index, ≥ 40mL/m^2	2.35 (1.18–4.68)	0.016	1.17 (0.42–3.28)	0.768
CV score, ≥ 3	5.21 (2.41–11.23)	< 0.001	1.70 (0.39–7.41)	0.480
Bradycardia (Holter), < 60/min	3.25 (1.32–7.97)	0.010	2.37 (0.89–6.37)	0.086
No antiarrhythmics	2.32 (1.17–4.60)	0.016	1.80 (0.58–5.56)	0.305
TEE	1.00 (0.51–1.96)	0.998		

CI = confidence interval, SSE = stroke and/or systemic embolism, LVEF = left ventricular ejection fraction, LA = left atrium, CV = CHA_2DS_2-VASc, TEE = transesophageal echocardiography.

persistent AF/AFL who underwent ECV. Among these, multivariate analysis revealed clinical significance of female sex (HR, 3.99; 95% CI, 1.31–12.18; *P* = 0.015) and history of SSE (HR, 3.62; 95% CI, 1.17–11.18; *P* = 0.026) (**Table 4**, **Fig. 1**). Lists of complications of female patients or those with a history of SSE during and after ECV for persistent or long-standing persistent AF/AFL during the 1 year follow-up are presented in **Supplementary Table 2**.

DISCUSSION

This study revealed that the old age, female sex, history of DM, history of HF, history of SSE, low LVEF, high LAVI, high CV score, and bradycardia on Holter were related risk factors of complications in patients with persistent or long-standing persistent AF/AFL who underwent ECV for l-year follow-up. Notably, among these, female sex and a history of SSE were the most important risk factors.

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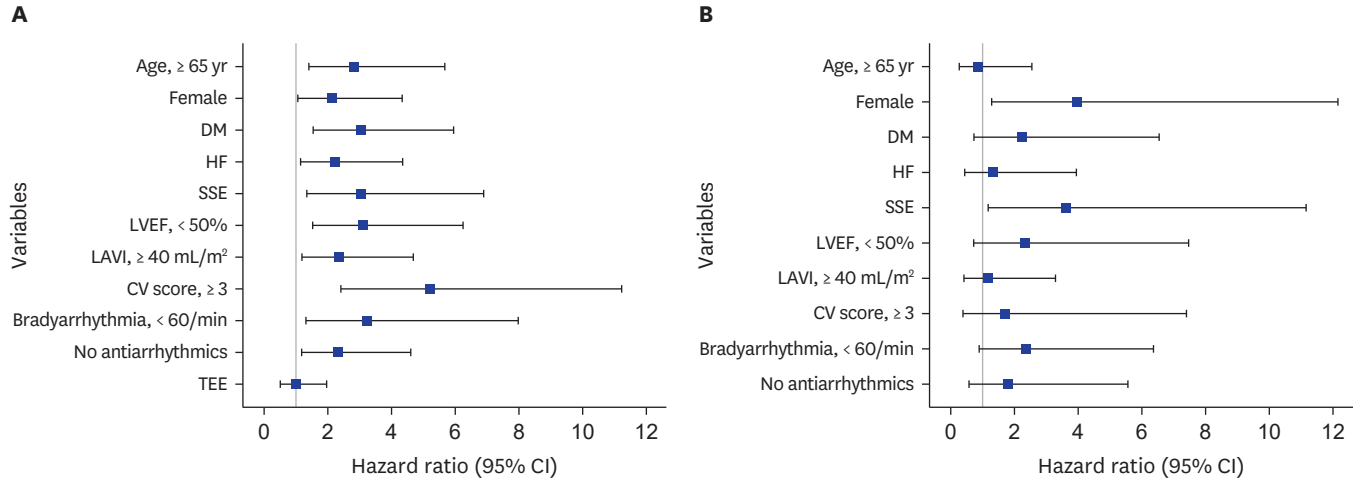


Fig. 1. Plot of hazard ratios and 95% CIs for (**A**) univariate and (**B**) multivariate analysis of risk factors of complications in patients with persistent or long-standing persistent atrial fibrillation/atrial flutter who underwent electrical cardioversion.
DM = diabetes mellitus, HF = heart failure, SSE = Stroke and/or systemic embolism, LVEF = Left ventricular ejection fraction, LAVI = left atrium volume index, CV = CHA2DS2-VASc, TEE = transesophageal echocardiography, CI = confidence interval.

AF management via rhythm control strategy using catheter ablation has received increasing attention.[1,2] Several studies showed a survival benefit, a lower hospitalization rate for worsening HF by the catheter ablation, and improved symptom scores and clinical outcomes by rhythm control for AF.[3,4,13] Accordingly, AF ablation should be considered in symptomatic patients with AF and those with AF with HF.[1,2] However, ablation outcomes are still controversial, and the effects of antiarrhythmics are inferior to those of ablations. Notably, the 1-year maintenance rate of SR without antiarrhythmic therapy was reported to be 67–74% for paroxysmal AF and 43% for persistent AF.[14] Furthermore, implantation of a pacemaker, ICD or CRT device may be required in cases of serious complications related to the procedure, depending on the underlying patient's rhythm status or general condition. The cost and agony of the patient and medical team for rhythm control is another problem.[5] Therefore, suitable patient selection and relatively economical and effective tools for rhythm control are important for optimal rhythm control strategies.[6,7] ECV could be an attractive choice for the initial rhythm control strategy for persistent or long-standing persistent AF/AFL, because of its ease, low cost, and effectiveness.[1,8] ECV can be used to control unstable vital signs or uncontrolled symptomatic states for acute arrhythmia, help unmask the underlying rhythm status, identify the true impact of AF, and maintain long-term rhythm control even without medications.[15,16] As part of rhythm control management, guidelines suggest that cardioversion should be considered in symptomatic patients with persistent AF.[2]

However, the success rate of ECV is reported to be 67–90% for persistent AF. Maintenance of SR could be influenced by ongoing acute conditions, LA size, duration of AF/AFL, immediate recurrence of AF, history of unsuccessful ECV, or other comorbidities.[1,17] Though rates of significant complications are low, ECV can cause thromboembolic and arrhythmic complications.[9] Acute and late adverse events are reported in 3.6% and 8.2% of patients after ECV for AF, respectively, which could be more frequent in patients with severe underlying heart disease.[17] The complicatoin rate (3.9%) in this study aligns with these results, even after 1 year of follow-up after ECV. Although some complications, such as late-developed MI, SSE, or non-cardiac issues-related death due to cholangiocarcinoma, may not be directly related to ECV, these complications occur in the middle of the active rhythm control state. Therefore,

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the identification of patients at high risk of ECV could alert the determination of rhythm control for these patients with AF, and a cautious approach could be adopted for these patients.[10,11] Thromboembolic complications after ECV for AF range from 5% to 7%, which decrease to 0.7% to 0.8% with adequate anticoagulation.[7] Therefore, anticoagulation should be maintained before and after ECV and continued lifelong, depending on the CV score of the patient.[9] In this study, most patients received adequate anticoagulation with DOACs or warfarin, and embolism-related complications (MI and SSE) occurred in five patients. No statistically significant differences were observed in the prescription and duration of anticoagulation between the complication and no-complication groups. Clopidogrel was prescribed more frequently in the complication group; however, the sample size for the analysis was limited. Bleeding complications are another conflicting issue and an ineluctable event in patients on anticoagulants. Early identification and proper management is crucial. For reducing bleeding complications, modifiable bleeding risk factors should be controlled and a balance between thromboembolic and bleeding risk should be targeted.[2]

Bradycardia complications by ECV are reported in 0.8% to 1.5% of patients with persistent AF, and post-cardioversion bradyarrhythmias can be later treated with the implantation of a permanent pacemaker in > 40% of patients.[11] In this study, pacemakers were implanted in 12 patients, and bradycardia on Holter was one of the risk factors for major complications of ECV, although the average heart rate on Holter did not differ between the groups. Slower atrioventricular (AV) conduction during AF might reflect issues in the AV node, which may involve the rest of the conduction system and sinus node, and the ECV might indicate sick sinus syndrome (SSS).[9,18] However, tachycardia bradycardia syndrome is another indication for pacemaker implantation, which might have influenced the average heart rate in this study. Analysis of the requirement of pacemaker implantation was impossible owing to a lack of information and limited cases. Notably, dramatic reductions in heart rate after ECV can cause ventricular arrhythmias.[6,19] Electrical remodeling and increased sympathetic activation may be associated with susceptibility to VF associated with post-AF cardioversion.[19,20] In this study, ICD and CRT were implanted in six and five patients, respectively. Among them, we reported an ICD implantation case due to critical VT, which might be related with severe bradyarrhythmia after ECV.[6] Unfortunately, other causes of implantation of ICD or CRT could not be identified due to the retrospective nature of this study. However, five cases required ICD and two cases required CRT implantation within three months of ECV, which suggests unstable cardiac rhythm might influence these results. Three patients experienced hospitalization for aggravated HF six months after ECV, which suggests ECV might not be directly related with these events. However, HF could be aggravated by bradyarrhythmia, antiarrhythmics, and general condition. Proper management and careful follow-up is essential in high-risk patients, especially with HF with reduced ejection fraction, to prevent AF recurrence.[2] Randomized large-scale studies on rhythm control in patients with persistent or long-standing persistent AF with slow ventricular response (SVR) remain lacking, and a meticulous review and selection criteria for rhythm control are required for persistent or long-standing persistent AF with SVR.[21,22] No use of antiarrhythmics before ECV was a risk factor for major ECV complications in this study. However, this result should be interpreted with caution because of selection bias. Antiarrhythmic prescriptions are dithered for bradycardia, and class Ic antiarrhythmics are contraindicated in patients with HF or other significant structural heart diseases. Our findings further revealed that flecainide was rare prescribed in the complication group, which indicates the possibility of selection bias. Ideally, all antiarrhythmic therapies should be discontinued when sinus node function is investigated. However, patients are frequently prescribed antiarrhythmics before ECV in the

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belief that immediate relapses can be reduced and the chance of maintaining SR increased. SVR by using of beta-blocker, digoxin, or other antiarrhythmics does not increase the risk of bradycardia complications, and pre-treatment with antiarrhythmics can improve ECV effectiveness.[2,11,23,24] Although some debate exists regarding heart rate control before ECV in patients with persistent or long-standing persistent AF, ECV should be performed more cautiously in patients with SSS, AV conduction disturbances, or prolonged QTc.[2]

In this study, female sex and a history of SSE were the most important risk factors of complications in patients with persistent or long-standing persistent AF/AFL who underwent ECV. Female patients with AF showed an increased risk of stroke, sinus node dysfunction requiring permanent pacemaker implantation, and death compared to male patients, even after adjusting for differences in stroke risk factors and anticoagulants. Biological distinction, extent of atrial fibrosis, differences in distribution, manifestation, combined underlying conditions, and differences in anticoagulants treatment are suggested as hypotheses for these differences.[25] Stroke and ischemic heart disease have several common risk factors. Underlying cardiac diseases increase the risk of stroke, which can provoke autonomic disturbances and predispose patients to cardiac complications such as MI, arrhythmias, and HF.[26] In this study, CIED implantation and major bleeding events were the main complication in female (11/15 cases, 73%) and patients with a history of SSE (8/10 cases, 80%). Additionally, two cardiovascular deaths (2/2 cases, 100%) occurred in these patients, which suggests cautious ECV approach should be adopted for these high risk patients (**Supplementary Table 2**).

The guidelines suggest favoring rate control in following conditions: older age, longer history of AF, fewer symptoms, early controlled heart rate, larger LA, less left ventricle function, and less aortic valve regurgitation.[1] Additionally, increased cardiac size, digoxin use, HF, and decreased LVEF were found to be associated with failed ECV in patients with persistent or long-standing persistent AF/AFL in our previous observational study.[5] Therefore, these risk factors should be considered when deciding between rate and rhythm controls. When rhythm control is adopted for patients with persistent or long-standing persistent AF/AFL, a prudent approach and preemptive strategies are required before deciding rhythm control especially for these high risk patients. Guideline-directed anticoagulation, deliberate selection of antiarrhythmics, and careful follow-up schedule should be undertaken. Relatively low risk procedure such as pulsed field ablation could be a good option, or sometimes rate control could be a reasonable choice when considering the modest success rate of rhythm control for long-standing persistent AF. Further research and large-scale randomized prospective studies are required to obtain more accurate clinical results for patients with rhythm control in persistent or long-standing persistent AF/AFL.

This study has some limitations. First, this was a retrospective observational study, and the sample size in the complication group was relatively small. Therefore, selection bias may have influenced the results, along with the residual or unmeasured confounding factors. However, the complication rate in this study was similar to the results of other studies, and the enrolled patients from nine major tertiary medical institutions were relatively well-controlled. Second, we could not identify all the underlying causes of implantation of CIEDs due to the retrospective nature of the data acquisition. Especially, implantation of ICD or CRT might be unrelated to ECV. However, we think complication occurrence during and within three months of ECV could strongly suggest a relation with it. A total of 24 complications (59%) occurred during and three months of ECV. When considering the

CIED implantations only, 17 CIEDs were implanted within the same period, and one ICD was upgraded from a permanent pacemaker due to VT/VF at six month from ECV. In summary, total 18 CIEDs (78%) were implanted within three months of ECV or related with ECV, which could represent a compelling correlation between complication occurrence and ECV (**Supplementary Table 1**). Third, we attempted to identify risk factors for complications of ECV in persistent or long-standing persistent AF/AFL for 1 year. Therefore, some complications might be directly unrelated to ECV, and the results after 1 year are unknown. However, this study was conceptualized for adopting more cautious approach for high-risk patients of rhythm control. Therefore, the 1 year of active rhythm control follow up after ECV may have its own clinical significance. Lastly, we only analyzed complications of ECV, because ECV is an effective initial rhythm control method for persistent or long-standing persistent AF/AFL. Therefore, other rhythm control methods such as catheter/surgical ablation for AF/AFL, or a CIED implantation with antiarrhythmics were excluded from this study. Further studies are required to identify the risk factors of complications of all rhythm control methods for persistent or long-standing persistent AF/AFL.

Old age, female sex, history of DM, history of HF, history of SSE, low LVEF, high LAVI, high CV score, and bradycardia on Holter were related risk factors of complications in patients with persistent or long-standing persistent AF/AFL who underwent ECV. Among these, female sex and a history of SSE were the most important risk factors, and a cautious approach should be adopted for these patients.

SUPPLEMENTARY MATERIALS

Supplementary Table 1

Timing of complications during and after electrical cardioversion for persistent or long-standing persistent atrial fibrillation/atrial flutter during 1 year follow-up

Supplementary Table 2

Lists of complications of female and a history of SSE during and after electrical cardioversion for persistent or long-standing persistent atrial fibrillation/atrial flutter during 1 year follow-up

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