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Low cardiovascular event rate and high atrial fibrillation recurrence rate one year after electrical cardioversion

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SOUHRN

Kontext: U pacientů s fibrilací síní se k obnově sinusového rytmu běžně provádí elektrická kardioverze. Dlouhodobé hodnoty incidence klinických příhod a udržení sinusového rytmu po elektrické kardioverzi však nejsou přesně známy. Tato monocentrická studie zkoumala jednoroční incidenci a rizikové faktory vzniku kardiovaskulárních příhod a recidivy fibrilace síní.
Metody: Do prospektivní studie bylo zařazeno 188 pacientů s fibrilací síní, u nichž byla provedena elektrická kardioverze. V následném jednoročním sledování, jehož se zúčastnili pacienti po kardioverzi a jejich praktičtí lékaři, byla hodnocena incidence klinických a arytmických příhod. Údaje získané od pacientů a praktických lékařů byly spojeny a výsledky byly analyzovány pomocí software PSPP 0.8.5.
Výsledky: Úspěšnost elektrické kardioverze dosáhla 90,4 %. Do jednoho roku po kardioverzi prodělal jeden pacient (0,6 %) infarkt myokardu, u tří pacientů (1,9 %) proběhla cévní mozková příhoda/transitorní ischemická ataka (TIA), tři pacienti (1,9 %) zemřeli a u tří pacientů (1,9 %) došlo ke krvácivé příhodě vyžadující hospitalizaci. Jediným faktorem vykazujícím tendenci ke zvýšení rizika kombinace infarktu myokardu, cévní mozkové příhody/TIA a krvácení (p = 0,096) byla přítomnost diabetes mellitus. Při kontrolách uvedlo 30,0 % pacientů epizody fibrilace síní a po jednom roce jich 62,2 % popsalo alespoň jeden případ paroxysmální fibrilace síní. Podíl pacientů, u nichž byla provedena další kardioverze po původní hospitalizaci, dosáhl 32,5 %. Mezi faktory významně zvyšující riziko recidivy fibrilace síní patřily cévní mozková příhoda/TIA v anamnéze (p = 0,014) a echokardiograficky prokázaný zvýšený index objemu levé síně (p = 0,039). Tendence ke zvýšenému riziku byla nalezena i při větším průměru levé síně (p = 0,087).
Závěry: Incidence kardiovaskulárních příhod během jednoho roku po elektrické kardioverzi byla nízká. Přes vysokou bezprostřední úspěšnost elektrické kardioverze se stabilní sinusový rytmus podařilo dlouhodobě udržet pouze u malého počtu pacientů.

ABSTRACT

Background: Electrical cardioversion is widely used to restore sinus rhythm in patients with atrial fibrillation. However, the long term clinical event and sinus rhythm maintenance rates following electrical cardioversion still remains unclear. This study evaluated one year incidence and risk factors for cardiovascular events and atrial fibrillation recurrence in a single center clinical practice.
Methods: In a prospective study 188 patients with atrial fibrillation who underwent electrical cardioversion were enrolled. Patients and their primary care physicians were followed up one year after cardioversion and patient clinical and arrhythmic event rate was evaluated. Data obtained from patients and general practitioners were combined and the results were analyzed with PSPP 0.8.5. software.

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Results: Electrical cardioversion success rate was 90.4%. Within a year after cardioversion one patient (0.6%) suffered myocardial infarction, three patients (1.9%) had a stroke/transitory ischemic attack (TIA), three patients (1.6%) died and three patients (1.9%) had a bleeding event that required hospitalization. The presence of diabetes mellitus was the only factor with a tendency to increase the risk of combined event of myocardial infarction, stroke/TIA and bleeding ($p = 0.096$). At follow up 30.0% of patients reported having atrial fibrillation and within a year 62.2% had suffered at least one atrial fibrillation paroxysm. The proportion of patients who underwent additional cardioversions after the initial hospitalization was 32.5%. The factors that significantly increased the risk of atrial fibrillation recurrence were history of stroke/TIA ($p = 0.014$) and increased left atrial volume index on echocardiography ($p = 0.039$). Greater left atrial diameter had a tendency towards an increased risk ($p = 0.087$).
Conclusions: Cardiovascular event rate one year after electrical cardioversion was low. Electrical cardioversion had a high immediate success rate, however, maintenance of stable sinus rhythm in the long term was low.

Keywords:
Atrial fibrillation
Cardiovascular events
Electrical cardioversion

Introduction

Atrial fibrillation is the most frequently observed cardiac rhythm disorder with a prevalence of approximately 2% in the population [1]. Studies have shown that the incidence and prevalence of atrial fibrillation tends to increase over time [2,3] due to increasing average life expectancy and improved diagnosis and treatment of atrial fibrillation [4].

Atrial fibrillation is a risk factor for thromboembolic complications and it has been estimated that it may increase the risk of suffering from a stroke even fivefold [5]. In addition, the severity of strokes caused by atrial fibrillation is greater compared to ischemic cerebrovascular events in patients with carotid artery disease [6] due to the embolization of larger particles in patients with atrial fibrillation [6,7]. Patients suffering from atrial fibrillation have higher cardiovascular and non-cardiovascular mortality rate and atrial fibrillation can cause or worsen the course of congestive heart failure [8–10].

Electrical cardioversion is widely used to restore sinus rhythm in patients with atrial fibrillation. However, even after the restoration of sinus rhythm these patients are on a higher risk of suffering from thromboembolic complications. Therefore oral anticoagulation therapy is the mainstay of treatment in patients with a high risk of stroke [1]. This study was initiated to evaluate one year incidence and risk factors for cardiovascular events and atrial fibrillation recurrence in patients who underwent electrical cardioversion in a single center clinical practice.

Methods

Study participants

This prospective study was conducted from October 2015 to April 2016 in a single center University Hospital. A total of 188 consecutive patients who underwent synchronized direct-current cardioversion were enrolled. Patients were referred to the cardioversion unit after confirmation of atrial fibrillation by electrocardiographic recording by their primary care physician or from the emergency department. The study was approved by an institutional review committee. All patients gave an informed consent. The inclusion criteria were: age ≥18 years, confirmed atrial fibrillation on a 12-lead electrocardiogram, planned or performed sinus rhythm restoration by synchronized direct-current cardioversion at the index hospitalization. Patients with the anticipated life expectancy of less than one year, with contraindications for undergoing electrical cardioversion and patients with spontaneous or sinus rhythm restoration after pharmacological therapy were excluded from the study. During the index hospitalization patient demographic, echocardiographic, electrocardiographic and clinical laboratory data were collected.

Before electric cardioversion 12-lead electrocardiography was recorded and the diagnosis of atrial fibrillation was confirmed according to the standard criteria. Synchronized direct current cardioversion was performed according to the guidelines and was defined as successful if stable sinus rhythm was obtained and patient was discharged with sinus rhythm. Patients with a definite duration of atrial fibrillation <48 h underwent acute restoration of sinus rhythm by synchronized direct-current cardioversion without performing transoesophageal echocardiography before the procedure. In patients with atrial fibrillation lasting ≥48 h electrical cardioversion was performed after anticoagulation therapy pretreatment according to the ESC guidelines for the management of atrial fibrillation [1] or after the exclusion of atrial thrombus by transoesophageal echocardiography. At the discharge patients were prescribed anticoagulant therapy and long-term anticoagulation was prescribed in patients at high risk for stroke as recommended in the guidelines [1].

Clinical event assessment

One year after cardioversion patients were followed up by telephone calls. A national health registry was used to obtain enrolled patients' general practitioner email address and a patient follow-up questionnaire was sent. The main clinical events that were evaluated in the phone conversation with patient and in general practitioner's questionnaire were: suffering from a stroke, transitory ischemic attack (TIA), myocardial infarction, significant bleeding that required hospitalization, atrial fibrillation recurrence and repeat cardioversions within a year after the initial cardioversion. Additional information collected from the patient was: demographic parameters and current pharmacotherapy. All-cause mortality was evaluated from the information obtained from general practitioners and by the use of a national health registry. Information obtained from the questionnaires filled by general practitioners was combined with data obtained from patients and used in data analysis. A total

of 28 patients were excluded from the final data analysis due to failure in obtaining follow-up information. A national registry confirmed death in three of these patients.

Statistical analysis was performed using PSPP 0.8.5 software. Continuous variables were expressed as mean ± standard deviation (SD) and were analyzed with independent t-test. Categorical variables were expressed as percentages and frequencies. Fisher's exact test was used to assess the differences between groups with categorical variables. Results with $p < 0.05$ were considered statistically significant. Univariate logistic regression analysis was performed to examine the predictors associated with one year risk of atrial fibrillation recurrence and the combined event of myocardial infarction, stroke/TIA, significant bleeding and all-cause death.

Results

Patient population

Patient baseline characteristics are shown in Table 1. Mean patient age was 65.4 years. Majority of the patients (57.7%) had a history of at least one cardioversion and 81.4% were on a high risk of stroke with ≥2 points in CHA_2DS_2-VASc score (congestive heart failure or left ventricular dysfunction, hypertension, age ≥75 (doubled), diabetes, prior ischemic stroke, TIA or thromboembolism (doubled), vascular disease, age 65–74, gender (female)).

Table 1 – Patient baseline characteristics.

	Total (%)
Gender – male	112 (59.6)
Age (mean ± SD)	65.4 ± 10.1
Weight (mean ± SD)	93.6 ± 20.1
Body mass index, kg/m² (mean ± SD)	31.2 ± 5.7
Smoking	19 (10.1)
Arterial hypertension	163 (89.1)
Diabetes mellitus	30 (16.0)
Congestive heart failure	134 (76.1)
Cardiac pacemaker	18 (9.6)
History of	
Heart surgery	5 (0.5)
Percutaneous coronary intervention	25 (13.3)
Stroke/transient ischemic attack	13 (6.9)
Radiofrequency catheter ablation	7 (3.7)
Cardioversion	105 (57.7)
Pharmacological only	28 (15.4)
Electrical	77 (42.3)
CHA_2DS_2-VASc score	
0	8 (4.3)
1	27 (14.4)
≥2	153 (81.4)
Duration of atrial fibrillation	
<48 h	21 (11.2)
≥48 h	167 (88.8)

Table 2 – Clinical events at one-year follow-up.

	Total (%)
Myocardial infarction	1 (0.6)
Stroke/transient ischemic attack	3 (1.9)
Significant bleeding	3 (1.9)
All cause death	3 (1.6)
Radiofrequency catheter ablation (RFCA)	9 (5.5)
Atrial fibrillation after RFCA	3 (33.3)
Elective percutaneous coronary intervention	1 (0.6)
Cardiac pacemaker implantation	3 (1.9)
Hospitalization due to other causes	26 (16.3)

Clinical events at one-year follow-up

At follow-up one patient had suffered myocardial infarction and one had undergone elective percutaneous coronary intervention (Table 2). Three patients reported of being hospitalized due to significant bleeding. All three patients initially were on warfarin therapy. After the bleeding event, warfarin was replaced with a novel oral anticoagulant (NOAC) in two patients and one continued the use of warfarin. Three patients suffered a stroke. All of these patients had four points according to the CHA_2DS_2-VASc score. Although all of these patients were prescribed anticoagulation therapy after the cardioversion, one of them reported discontinuation at the follow-up. Three patients died due to non-cardiovascular causes. Diabetes mellitus showed a tendency ($p = 0.096$) towards correlation with combined event of myocardial infarction, stroke, significant bleeding or death. No other factors had any correlation with the risk of suffering from the combined adverse event.

Arrhythmic events

At the discharge 90.4% of patients had undergone successful cardioversion and had sinus rhythm. The percentage of patients who reported having sinus rhythm at follow was 70.0%. Within a year 62.2% of patients experienced at least one atrial fibrillation paroxysm and 25.5% of them had the diagnosis of permanent atrial fibrillation (Table 3). Additional cardioversions were performed in 32.5% of patients. The factors that significantly increased or showed a tendency to increase the risk of atrial fibrillation recurrence during a year are shown in Table 4.

Patient adherence to anticoagulation therapy

The use of anticoagulant therapy during the study is shown in Table 5. Anticoagulant therapy was prescribed to 98.9% of patients after cardioversion. At follow-up 33.8% of patients reported not using any anticoagulants and 81.1% of these patients were on a high stroke risk with ≥2 points in CHA_2DS_2-VASc score. No significant differences were observed in the risk of stroke ($p = 0.550$) and combined event rate ($p = 0.424$) in patients who discontinued *versus* continued the use of oral anticoagulation therapy. Patients who initially used NOAC compared

Table 3 – Atrial fibrillation (AF) recurrence at one-year follow-up.

	Total (%)
Atrial fibrillation present during follow-up	48 (30.0)
Patients with atrial fibrillation paroxysms during a year	102 (62.2)
One paroxysm	33 (32.4)
Two paroxysms	13 (12.8)
Three or more paroxysms	30 (29.4)
Patients with permanent atrial fibrillation	26 (25.5)
Additional cardioversions after the initial hospitalization	53 (32.5)
Of them – pharmacological cardioversion	9 (17.0)
Electrical cardioversion	44 (83.0)

to the users of warfarin, more frequently had stopped the use of anticoagulant therapy at follow-up (OR 3.21; 95%CI 1.31–7.90; p = 0.011). In patients with ≥2 points in CHA_2DS_2-VASc score the risk of anticoagulant therapy discontinuation was increased in the group of patients without atrial fibrillation recurrences during a year (OR 3.51; 95% CI 1.58-7.78; p = 0.002) (Table 6).

Discussion

In the present study low incidence of adverse clinical events in patients who underwent electrical cardioversion in our single center clinical practice was observed. A total of ten patients suffered either myocardial infarction, stroke/TIA, significant bleeding or death. The event rate in our study patient population are consistent with the low event rate reported in Flec-SL (Flecainide-Short Long Study) trial. It included atrial fibrillation patients who underwent elective pharmacological or electrical cardioversion and received anticoagulation therapy consistent to the local practice. At six-month follow-up the reported stroke/TIA rate was 0.9%, independent of the type of cardioversion used [11]. The estimated annual rate was 1.9% [11], which is in line with the 1.9% stroke/TIA rate in our study.

No risk factors that significantly increased the risk of the combined event were found. It could be due to the relatively low patient and clinical event count in our study. The presence of diabetes mellitus was the only factor that showed a non-significant tendency towards an increased risk of adverse clinical event at one year. In the FinCV (Finnish CardioVersion) study diabetes mellitus was shown to be an independent thromboembolism risk predictor. Diabetes mellitus significantly increased the risk in patients 30 days after acute electrical cardioversion of atrial fibrillation lasting less than 48 h when no anticoagulation therapy was used post procedure [12]. The non-significance found in our study could be attributed to the fact that almost all patients in our center were prescribed anticoagulation therapy at least four weeks after electrical cardioversion.

The rate of hospitalization due to significant bleeding was 1.9%. Compared to the 0.5% major bleeding rate 30 days after electrical cardioversion in a multicenter study [13] and the 30-day major bleed rate of 0.8% in Flec-SL

Table 6 – Factors associated with discontinuation of anticoagulant use at follow-up in patients with CHA_2DS_2-VASc score.

Factor	*P* value
Gender	0.437
Weight	0.249
Lower body mass index	0.068
Age	0.878
History of cardioversion before index hospitalization	0.220
Arterial hypertension	0.999
Smoking	0.534
Diabetes mellitus	0.805
Congestive heart failure	0.376
History of myocardial infarction	0.809
History of stroke/transient ischemic attack	0.716
No atrial fibrillation recurrence within a year	0.002

Table 4 – Factors that increased the risk of atrial fibrillation (AF) recurrence within a year.

	Patients without AF recurrence	Patients with AF recurrence	*P* value
History of stroke/transient ischemic attack (number of patients)	0	10	0.014
Left atrial volume index, mL/m^2	34.03	37.69	0.039
Left atrium diameter, mm	43.03	45.60	0.087
Low density lipoprotein cholesterol (LDL-C), mmol/l	2.93	2.60	0.032

Table 5 – Anticoagulant use during the study period.

Anticoagulant use	At hospitalization, n (%)	At discharge, n (%)	At follow-up, n (%)
Total	179 (95.2)	186 (98.9)	104 (66.2)
Warfarin	45 (28.7)	48 (25.5)	46 (29.3)
Dabigatran	66 (35.1)	64 (34.0)	22 (14.0)
Rivaroxaban	67 (35.6)	73 (38.8)	36 (22.9)
Apixaban	1 (0.5)	1 (0.5)	-

trial [11], we considered our one-year major bleeding rate as low. During the follow-up data collection, a trend in stopping anticoagulant use starting from four weeks post-cardioversion was noted. The study group consisted mainly of high thromboembolic event risk patients and 81.4% of them had CHA_2DS_2-VASc score ≥2. However, 33.8% of patients reported discontinuation of anticoagulant use and 81.1% of these patients were on a high stroke risk with ≥2 points according to CHA_2DS_2-VASc score. While the percentage of warfarin users at the discharge and at follow-up remained relatively the same, there was a significant decrease in the users of NOAC. Of those who discontinued the use of any anticoagulation therapy, 86% were NOAC users. NOAC, compared to warfarin have advantages of easier dosing and lack of need for anticoagulation effect monitoring. In addition, studies have shown that the adherence to therapy is higher in NOAC compared to warfarin using patients [14]. However, this study showed that the adherence to anticoagulation therapy in our patient population is decreased mostly in NOAC users. It could be speculated that the high anticoagulant therapy discontinuation rate could be the consequences of complex factors involving the patient, primary care physician and medication cost differences. Insufficient stroke risk factor assessment or the need of improvement in patient counseling regarding the importance of long term anticoagulant use in the primary care may contribute to the discontinuation of anticoagulant use. In addition, the complexity of treatment with warfarin and the significant cost differences between NOAC and warfarin may all lead to poor patient adherence and the decision to stop NOAC use instead of switching to warfarin treatment.

This study showed high rate of atrial fibrillation recurrence in our patient population. More than 62% of patients reported experiencing at least one atrial fibrillation paroxysm within a year and 32.5% of patients were hospitalized for repeat cardioversions. Our results are in line with other studies where it has been estimated that less than half of atrial fibrillation patients remain in stable sinus rhythm within a year after the initial cardioversion [15]. The factors that increased the risk of atrial fibrillation recurrence in the present study were a history of stroke/TIA and increased LAVI on echocardiography. It has been estimated that patients with LAVI <30 mL/m^2 have a greater possibility of maintaining stable sinus rhythm after a successful cardioversion in the long term [16]. Although statistical significance was not obtained in this study, a tendency towards greater atrial fibrillation recurrence risk was observed in patients with increased left atrium diameter. However, in the AFFIRM (Predictors of Long-term Maintenance of Normal Sinus Rhythm After Successful Electrical Cardioversion) study left atrial diameter >4.5cm was associated with the need for repeat cardioversions within a year after successful initial cardioversion [17].

This study has some limitations. It was conducted in a single center and with a relatively small sample size therefore the clinical outcome rates could not be attributed to a wider population. Clinical and arrhythmic events reported by patients should be interpreted with caution due to the lack of independent evaluation and confirmation. Due to the loss of follow-up the actual clinical event rates may differ.

Conclusions

Low clinical event rate one year after direct current cardioversion was observed in the study population. Electrical cardioversion had a high immediate success rate, however, maintenance of stable sinus rhythm in the long term was low. The factors that significantly increased the risk of atrial fibrillation recurrence were history of stroke/TIA and increased left atrial volume index on echocardiography. Although this study included mainly patients with high risk of stroke, anticoagulation therapy discontinuation was frequently reported at follow-up. Prescription of NOAC after cardioversion was an independent risk factor for anticoagulant therapy discontinuation.

Conflict of interest
None.

Funding body
None.

Ethical statement
Authors state that the research was conducted according to ethical standards.

Informed consent
I declare, on behalf of all authors, that informed consent was obtained from all patients participating in the study.

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