THE USE OF PACEMAKER DIAGNOSTICS FOR SUPPORTING THE ANTICOAGULATION TREATMENT MANAGEMENT

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Abstract

In this work, the analysis of data on atrial fibrillation (AF) burden from dual chamber pacemakers is used for supporting the anticoagulation treatment management. The aim is to evaluate the benefit of basic diagnostic functions to support oral anticoagulation therapy in patients with atrial fibrillation. These patients have increased risk of thromboembolism. If patients have an implanted pacemaker, the device's diagnostic features monitor the frequency and duration of atrial fibrillation episodes. This data can then be used for further decisions. Statistical data processing was performed on a group of 117 patients with an implanted dual chamber pacemaker. From these results, we evaluated the benefits of the algorithms. In the whole group, a trend was observed in increase of the AF burden between the two monitored periods. The increase of AF burden occurred in 17 patients, while the decrease occurred in 6 patients only. Using simple logic functions, the numbers of patients with different binary values of the presence of AF, the presence of oral anticoagulation therapy, the risk CHA_2DS_2-VASc score and the values of AF burden were determined. Thus, in the whole group of patients, the diagnostic functions of the implanted devices contributed to the change in oral anticoagulation therapy for 24% of patients.

Keywords

atrial fibrillation, tachyarrhythmias, pacemakers, anticoagulation, risk factors, diagnostics

Introduction

Atrial fibrillation (AF) is diagnosed in 1–2% of the population and its incidence is still increasing [1]. It is accompanied by increased morbidity and mortality, for example the risk of stroke is fivefold [2]. The general goal is to diagnose AF early and initiate the optimal treatment. Risk factors for AF are hypertension, heart failure, valve defects, cardiomyopathy, etc. AF affects the filling phase of the ventricles and impairs the patient's hemodynamics. Therefore, AF is associated with severe symptomatology, such as palpitations, dyspnea, increased fatigue and decreased ejection fraction. The most serious complication of AF is thromboembolism. During AF episodes, the atria are rapidly moved in an uncoordinated manner, which results in a slow blood flow and thus creating conditions for the formation of the thrombus. If a thrombus is released into the bloodstream, a cerebral artery blockage may occur. Artery occlusion prevents part of the brain from the oxygenation, causing ischemia and damage of the tissue. Thromboembolic complications associated with AF tend to be difficult and have poor survival prospects. Therefore, oral anticoagulation therapy (OAT) in patients with AF is one of the key therapeutic. The results of the study [3] show that even short episodes lasting more than 5.5 hours per month are associated with an increased risk of thromboembolism.

AF is a supraventricular arrhythmia characterized by rapid, uncoordinated, yet electrically detectable atrial action. It is caused by the rapid and chaotic spread of electrical excitations in both atria. The electrocardiogram can detect waves of an isoelectric line or a fibrillation wave with a speed exceeding 300/min, without any clear P-waves. The loss of coordinated atrial contraction results in reduced pumping capacity, blood congestion, and usually accelerated transmission of excitations to the ventricles. The result can be deterioration in physical performance. However, the risks associated with AF are the same in patients with asymptomatic episodes as in patients with symptomatic episodes.

AF is divided according to duration into paroxysmal (spontaneously ending episodes within 48 hours), persistent (lasting more than 7 days and requiring drug or electrical version), long-term persistent (lasting more than a year, with the possibility of adjusting the heart rhythm) and permanent which cannot be interrupted by

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cardioversion or recurs after cardioversion within 24 hours [2, 4]. Monitoring of ECG using the Holters and other recorders is not sufficient for paroxysmal episodes; therefore device diagnostic functions can be used in patients with implantable pacemaker (PM). Nowadays, all implanted devices allow the detection of AF and the evaluation of the total AF burden in percentages. Many devices are also able to evaluate individual episodes, their duration and atrial rate. This evaluation has not only a theoretical output, but is also a key for indicating the introduction of OAT or its optimization. The indication for OAT is based on a consideration of the risk of embolic/bleeding complications in a particular patient, which is determined on the basis of risk schemes [5]. The current first choice drug for OAT is Warfarin. However, treatment with Warfarin raises concerns about bleeding events, the need for regular blood clotting checks. Interactions of Warfarin with other drugs and food are known. Because of the above, sometimes the OAT is not set even in patients at high risk of stroke [2, 5].

The so-called $CHADS_2$ score was used to evaluate the risks of thromboembolic complications. It is based on a point system, where 2 points are given for a past stroke/TIA (transient ischemic attack) and other four factors (chronic heart failure, hypertension, age, diabetes mellitus) are rated 1 point. Warfarin treatment was always used in patients with a score above 2. Patients at risk 0 are not indicated for any treatment. The $CHADS_2$ score proved to be limiting for patients with a score of 1 (moderate risk of thromboembolism), when OAT or anti-aggregation treatment is at the discretion of the physician. Here, the newer CHA_2DS_2-VASc stratification scheme was used, adding points for age 65–74 years, female sex and either coronary artery disease (CAD) or peripheral artery disease (PAD) to the original $CHADS_2$ score. This scheme has a higher predictive value for determining the risks of thromboembolism in patients at moderate risk for CHA_2DS_2-VASc = 1 [2, 5].

Patients indicated for implantation of dual chamber pacemaker were included in our group. In addition to the basic pacing function, the devices also have diagnostic features that monitor the patient's heart rate in both right chambers in the periods between the patient follow-ups. The devices are equipped with automatic mode switch. If detected atrial activity exceeds a set value, the device switches the pacing mode from a tracking mode to a non-tracking mode. The purpose of this feature is to protect the patient from the conduction of pathological high atrial rates to ventricles. The switching of the mode is related to the detection of the atrial arrhythmia and the subsequent evaluation of the duration of the arrhythmia and the recording of the episode in the device's memory. Current algorithms can be divided according to the method of AF detection. One option is the rate cut-off criterion, which senses atrial activity. Another method uses an average rate calculated from the running window. A third alternative is a sensor for detecting and distinguishing physiological rhythm from atrial tachycardia based on atrioventricular intervals. The parameter AF burden, evaluated and used in the work, is expressed as a percentage of the time performed in the mode-switch [6, 7].

Methods

A consecutive group of 117 patients who underwent PM implantation over a period of 11 months was evaluated. The patients were followed-up one month after implantation (period "A" i.e. implantation + 30 days) and seven months after implantation (period "B" i.e. from the 1st follow-up + 6 months). The PM setting was kept at the manufacturer default values, including the sensitivity of the atrial channel.

Metric quantities were described by means and standard deviations, categorical quantities were expressed as percentages. Subgroups of patients were compared by unpaired two-tailed t-test (for continuous variables). AF burden time changes were assessed by paired two-tailed t-test, $p < 0.05$ were considered statistically significant.

There were 117 patients in the evaluated group, of which 74 were men. The mean age was 73 ± 11 years. The CHA_2DS_2-VASc score evaluated was 3.4 ± 1.6 (range 0–8, median 3, interquartile range 3–4). In line with current clinical recommendations, the need for OAT in AF is defined for patients with CHA_2DS_2-VASc above 1. A total of 102 (87%) patients were in this range. The prevalence of each risk component was as follows: heart failure (10%), hypertension (84%), age 65–75 (33%), age above 75 years (51%), diabetes (26%), stroke/TIA (8%), CAD/PAD (37%), female gender (37%).

Of the 49 patients (42% of the total) with AF diagnosis were 5 patients (10%) in the low-risk range according to the CHA_2DS_2-VASc score (CHA_2DS_2-VASc < 1). None of them used OAT. Furthermore, 9 (18%) patients had CHA_2DS_2-VASc above 1 (high-risk score) and these patients were without OAT treatment. The remaining 35 (72%) patients also used OAT in the high-risk CHA_2DS_2-VASc score. Thus, the OAT treatment was used in 35/44 (80%) of indicated patients.

Of the 68 patients (58% of the total) without a known AF diagnosis, 16 (24%) patients used OAT for other reasons, and the remaining 52 (76%) patients without OAT. The prevalence of high risk CHA_2DS_2-VASc score (> 1) in patients without AF diagnosis and without OAT was 46/52 (88%).

AF burden was evaluated after the 1st month (period "A") and after the 7th month (period "B"). Values higher than 5.5 hours in 30 days (i.e. > 0.76%), which are associated with a significant thromboembolic risk, were considered as high AF burden [3].

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Results

Within the whole group of patients, a trend was observed in the increase of the AF burden in period "B" versus period "A" (see Fig. 1). The increase of AF burden occurred in 17 patients, while the decrease occurred in 6 patients only, see Table 1.

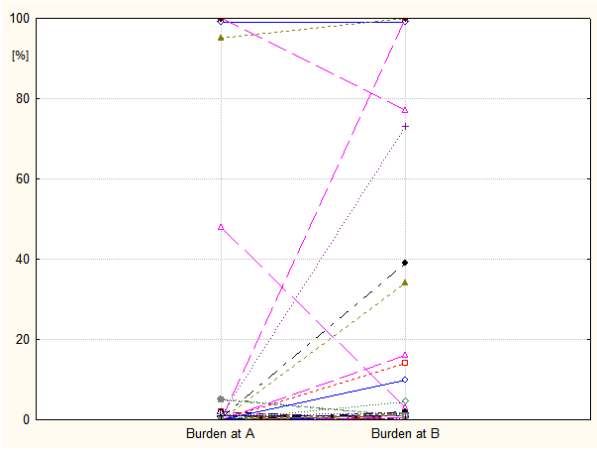

Fig. 1: The comparison of the AF burden in period "B" and period "A".

Table 1: The increase/decrease of AF burden.

		High AF burden at "B"	
		Yes	No
High AF burden at "A"	Yes	25	6
	No	17	69

The percentage increase of AF burden was 16.2 ± 35.2% in period "B" versus 14.3 ± 34.4% in period "A" (p = 0.12) both within 30 days (Fig. 2). Expression in absolute time values is 116 ± 253 hours versus 103 ± 248 hours in 30 days (p = 0.12). Using just a subgroup containing only the patients with AF burdens < 10% in period "A" (n = 100), then the increase of AF burden in period "B" versus period "A" is significant 3.1 ± 13.3% versus 0.3 ± 0.8% (p = 0.03) both within 30 days (Fig. 3). Expression in absolute time values is 22.5 ± 96.1 hours versus 1.9 ± 5.8 hours in 30 days (p = 0.03).

Using the logical sum (OR), logical product (AND) and negation function (NOT), the numbers of the patient in subgroups according to AF presence, CHA_2DS_2-VASc score, AF burden and the presence of OAT were determined:

– Among the 35 patients with AF diagnosis AND use OAT AND CHA_2DS_2-VASc score in the risk zone (> 1), there were 11 (31%) patients who had low (< 0.76%) AF burden in both follow-up periods. Even 7 of these patients had zero burdens. If this trend persisted during long-term follow-up, it would be possible to discontinue OAT in these 11 patients;
– Among the 14 patients with AF diagnosis AND NOT use OAT, there were 6 (43%) patients who had a high AF burden above 0.76% in at least one of the follow-up periods. Of these, 5 patients had a CHA_2DS_2-VASc score in the risk zone and are probably indicated for OAT;
– Among 52 patients with NOT AF presence AND NOT use OAT, there were 13 (25%) patients who had a high AF burden (> 0.76%) in at least one of the follow-up periods "A" or "B". Of these, 12 patients had a CHA_2DS_2-VASc score in the risk zone and are probably indicated for OAT.

A change in anticoagulation based on device memory data is indicated in 28 patients (24% of the total group).

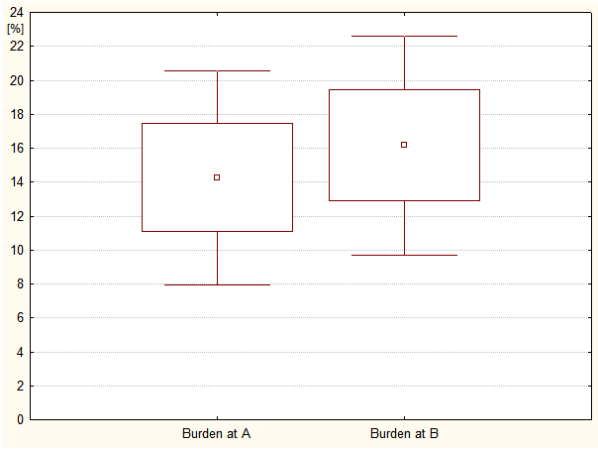

Fig. 2: The increase of AF burden in period "B" versus period "A" for the whole study group (n = 117), mean ± standard error (box) ± 0.95×confidence interval (whiskers).

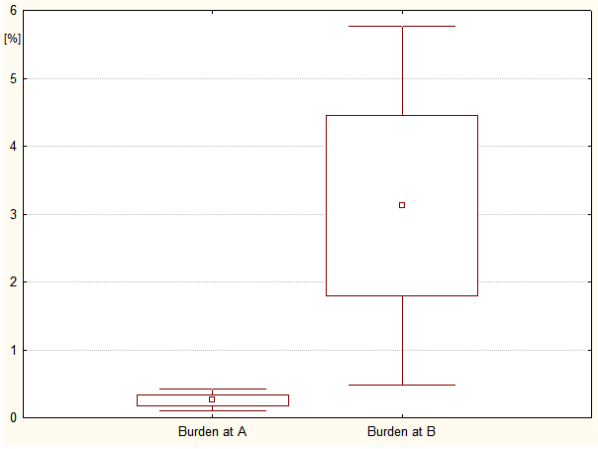

Fig. 3: The increase of AF burden in period "B" versus period "A" for the subgroup only containing the patients with AF burdens < 10% (n = 100), mean ± standard error (box) ± 0.95×confidence interval (whiskers).

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Discussion

The whole group of patients had a high thromboembolic risk in context of AF, the group also included patients with a previous history of AF. The results showed that there was a significant progression of AF burden in the early post-implantation period. However, the results do not indicate that any of the simple characteristics are a significant predictor of AF increase.

In the whole group of patients, episodes of AF with an implanted device indicated a change in OAT in 24% of patients. In fact, treatment was later adjusted in 6 out of 12 patients without AF diagnosis and without OAT with a CHA_2DS_2-VASc score in the risk zone, which had a high AF burden in at least one follow-up period. Warfarin was indicated in four cases and Pradaxa (dabigatran) was used in two patients. None of these patients reported significant problems that could be related to AF episodes. Warfarin was used in all five patients with AF diagnosis who did not use OAT with high-risk CHA_2DS_2-VASc score and high AF burden in at least one follow-up period. In two patients who were diagnosed with AF and were taking OAT but had a low AF burden in both follow-up periods, Warfarin was discontinued and replaced with antiplatelet therapy only.

The limitation of this work is that the 0–1 month period "A" was considered as a reference for monitoring the increase of AF burden in the follow-up period. However, the first post implantation month already asserts a negative effect of pacing and the overall effect of pacing on the development of AF increase is rather underestimated. A number of studies (PASE, CTOPP, the so-called Danish study) have demonstrated a negative effect of ventricular pacing (VVI) on the development of AF compared to physiological pacing (AAI, DDD) [8]. The percentage of ventricular pacing and its overall effect on the development of AF increase was not evaluated. Also the minimum duration of an AF episode to exclude false-positive detections was not established, while up to 17% of positive false detections of AF in episodes lasting 6 to 30 min according to the ASSERT study [9].

Conclusion

Algorithms for detecting atrial fibrillation may be useful for the diagnosis of atrial fibrillation episodes and management of further treatment. Again, rigorous individualization of programming and use of diagnostic detection algorithms for implanted systems is necessary. This study was limited to patients indicated for implantation of dual chamber pacemakers only, but the results are of course also valid for patients with defibrillators or resynchronization therapy. Algorithms for the detection of AF have clinical benefit in optimizing OAT in patients with asymptomatic episodes.

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