The role of the implantable atrial cardioverter-defibrillator

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Atrial and dual-chamber defibrillators with atrial antitachycardia functions represent an emerging option for the treatment of patients with drug-refractory atrial fibrillation. Atrial cardioversion has been demonstrated to be highly effective in treating spontaneous tachyarrhythmias and may reduce atrial fibrillation burden by preventing atrial remodeling. Device implantation has been associated with an improved quality of life and a reduced hospitalization rate. Patient selection and tailored device programming are critical as regards clinical outcome. The individual psychological profile analysis as well as the underlying heart disease and clinical patterns of atrial fibrillation represent the main drivers for the right strategy. Controlled studies are needed in order to define the subset of patients who can benefit more from device implantation.

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Introduction

The demonstration of the efficacy and tolerance of endocavitary low-energy cardioversion[1] to interrupt paroxysmal or persistent atrial fibrillation has been the main reason for the clinical introduction of implantable multifunction devices capable of delivering atrial shock. The first aims of atrial cardioversion are early interruption of atrial fibrillation and prevention of atrial remodeling which is judged to be the main mechanism involved in arrhythmia persistence and recurrence[2]. A stand-alone atrial defibrillator, in spite of documented good results as regards therapy efficacy[3] and arrhythmia recurrence reduction during the follow-up[4], is no longer available for clinical implantation.

The dual-chamber defibrillator

The dual defibrillator combines the features of conventional dual-chamber defibrillators with the capability of preventing, detecting and treating supraventricular tachyarrhythmias. Arrhythmia prevention is based on physiological pacing, rate responsive pacing, pacing prevention algorithms, and multisite atrial pacing, when applicable. Arrhythmia therapies include atrial antitachycardia pacing and cardioversion. Atrial cardioversion is the key feature of such a device. Shock for atrial tachyarrhythmias can be delivered either automatically or in manual mode under medical control or in patient activated mode using an external remote-control device. In case of automatic shock programming, several limits may be planned in order to prevent severe patient discomfort. First, a delay between arrhythmia onset and therapy delivery has to be programmed. Second, limitations of the time during the day in which therapy is allowed and of the maximal number of shocks may be introduced. Last, in case of no success, a time to stop new attempts has to be planned. A two-lead configuration (programmed shock pathway can + superior vena cava toward the right ventricle, with tilt 50%) or a three-lead configuration (with the additional coil into the coronary sinus) may be used. Atrial defibrillation is always synchronized to a non-refractory ventricular event and aborts in the presence of a high ventricular rate (minimum RR interval which allows shock delivery may be programmed no shorter than 400 ms).

Shock efficacy and tolerance were evaluated either in patients with[5,6] or without prior ventricular tachyarrhythmias (AF-Only group)[7]. A two-lead configuration was implanted in the large majority of patients candidate for defibrillator because of ventricular arrhythmias, while a three-lead system was selected in 60% in the AF-Only group. Atrial defibrillation threshold at implant was 6.1 ± 4.4, 4.3 ± 2.3 and 7.3 ± 5.0

J, in the three studies respectively. Unexpectedly in the AF-Only group there were no differences between the patients with the coronary sinus lead implanted (7.2 ± 5.0 J) and those without (7.5 ± 4.9 J). As a matter of fact, the choice of the lead system was not controlled and bias in patient selection may be responsible for this finding.

Efficacy of shock delivery was quite poor in patients with prior ventricular arrhythmias. Overall success rate was 74% (68% on atrial tachycardia and 76% on atrial fibrillation) in the Worldwide series[5], and 62.5% in the Italian study[6]. That could be partly dependent on the low number of treated episodes, actually 116 in 29 patients and 32 in 12 patients, respectively, but it may also depend on inappropriate shock programming. In the Italian study the delivered energy was on average 7.8 ± 4.1 J. Atrial shock effectiveness was directly related to the ratio between the actually delivered shock energy and the atrial defibrillation threshold at implant. In all but one ineffective shocks this ratio was ≤ 2. Looking at all treated episodes, for those in which this ratio was ≤ 2, shock efficacy was only 32%, while the success rate increased to 92% for ratios > 2.

In the AF-Only group, shocks were delivered to 1036 episodes in 107 patients. The success rate was quite good (86.7%). The adjusted estimate of therapy efficacy was 81.2%, with a 95% lower confidence bound of 76.8% and a 95% upper confidence bound of 84.9%.

As for the stand-alone atrial defibrillator experience, no ventricular arrhythmia induction was observed after atrial shock delivery in any published study.

Taking into account all data, shock acceptance may be considered quite good. Patient tolerance was better when an effective single shock was delivered than when multiple and/or ineffective shocks were released. Furthermore, a poor correlation was observed between shock tolerance and the amount of delivered energy. These data have recently been confirmed by Steinhaus et al.[1] who demonstrated that patients wearing a defibrillator could not distinguish differences in discomfort between shocks of 0.4 and 2 J, but perceived the second shock as more painful than the first, regardless of the energy delivered. It is worth noting that also a low-energy shock of 0.4 J may be supramaximal for the activation of pain fibers and skeletal muscle contraction. As a consequence, further attempts at reducing defibrillation threshold may not be followed by increased patient tolerance. The authors stressed the point that, in spite of discomfort involved, the majority of patients would tolerate low-energy internal shocks if delivered not more frequently than once a month. As a matter of fact, in the AF-Only group, the percentage of arrhythmia episodes treated with patient activated shock was stable during the follow-up, suggesting a good patient compliance.

Early recurrence of atrial tachyarrhythmia within a few minutes of the preceding episode may impair shock success rate. Such a problem was first reported in patients receiving a stand-alone atrial cardioverter[3] in whom early recurrence of atrial fibrillation did happen in 27% of the episodes. Similar percentages have been reported for patients receiving a dual-chamber defibrillator for ventricular arrhythmias[6,8].

Clinical outcome of patients with "atrial fibrillation only" indication receiving a dual-chamber defibrillator

One hundred and forty-six patients with drug-refractory atrial fibrillation without any prior ventricular tachyarrhythmia were enrolled in the Worldwide Jewel AF-Only trial[7]. Enrollment criteria included two symptomatic episodes of atrial fibrillation or flutter in the 3 months before implantation with at least one antiarrhythmic drug which failed in rhythm control during the last year. In the year before implant, patients received an average of 1.6 antiarrhythmic drugs for rhythm control and had an average of 2.3 cardioversions. At implant 63% was on antiarrhythmic drug therapy, with only minor changes during the follow-up. Seventy percent was on anticoagulants and 17% on antiplatelets. Structural heart disease had a high prevalence in the population. Twenty-three percent of the patients had a left ventricular ejection fraction < 35% and 46.5% was in NYHA functional class II or III. During the follow-up, system-related complications were observed in 16% of patients. The most common adverse event was lead dislodgment which was observed in 6.8% of patients. Kaplan-Meier 12-month estimate of survival was 97.6%. No death was classified as device-related. No sudden cardiac death was observed. Stroke occurred in 4 patients. Three of them were either not anticoagulated or inadequately anticoagulated at the time of the event. At 1-year follow-up, 94% of patients were in sinus rhythm. Atrioventricular junctional ablation because of poorly tolerated arrhythmia recurrence was performed in 9 patients (6.2%). Kaplan-Meier 12-month estimate of device survival (i.e. device implanted and at least one atrial therapy activated) was 91.3%. Twenty-nine percent of atrial arrhythmia episodes occurred < 1 min after the end of a prior episode. In this cluster early recurrence of atrial fibrillation and inappropriate classification of the end of the preceding episode were included. Such a percentage is not far from the incidence of early recurrence of atrial fibrillation in the patients who received a stand-alone atrial cardioverter[3] (27%). Reversal of tachycardiomyopathy to normal left ventricular function has been reported after atrial defibrillator implantation[9].

Interestingly, in AF-Only patients, during the follow-up, 16 spontaneous episodes of ventricular fibrillation and 51 of monomorphic ventricular tachycardia in 11 patients (7.6%) were appropriately detected by the device. An ongoing atrial tachyarrhythmia was present in 75% of ventricular tachycardia episodes, but no relationship could be found between atrial therapies and

ventricular arrhythmia induction. Ventricular arrhythmias either were successfully treated by ventricular antitachy pacing or shock or stopped spontaneously. This finding is different from what reported in the atrial cardioverter population in whom no ventricular events could be demonstrated. Actually, enrollment criteria for atrial cardioverter included normal left ventricular ejection fraction. Among the 11 patients who showed ventricular arrhythmias in the dual-chamber defibrillator group, only one had no structural heart disease and the mean left ventricular ejection fraction in this subgroup was 27 ± 13%.

We evaluated the impact of dual defibrillator implantation on the quality of life and resource utilization in 40 patients with drug-refractory atrial fibrillation without prior ventricular arrhythmias[10], followed up for 15 ± 4 months (range 12-30 months). Within 1 year after implant, arrhythmia-related hospitalization number decreased from 1.5 ± 2.0 to 0.4 ± 0.8 ($p < 0.01$) and 77% of patients were free from hospitalization. As regards the quality of life, symptom checklist/frequency and severity scale improved after implant for all items and the SF-36 questionnaire showed a significant improvement in physical activities because of health problems and social activities. Twenty-two patients (group A), who accepted atrial shocks, were assigned to early delivering of atrial shock after atrial fibrillation onset, either automatically (at night or at any time), or by using patient activator, or in hospital, manually delivered within 12 hours of the onset. Eighteen patients (group B), who did not accept shocks, because of shock-related fear and anxiety, had antitachy pacing therapies activated but atrial shock switched off. In the group B in-hospital manual shock was allowed, instead of electrical external cardioversion, when clinically recommended. The groups did not differ in pre-implant characteristics. The patients assigned to early delivery of atrial shock after atrial fibrillation onset (group A), when compared with the patients who did not accept atrial shock (group B), showed a significant long-term reduction of atrial fibrillation burden, a higher reduction of hospitalization number and a greater improvement of the quality of life.

Patient selection

In our opinion, from the clinical point of view, the best candidate for shock therapy should have these characteristics:
• paroxysmal or persistent atrial fibrillation with very uncomfortable and debilitating symptoms (> 24 hours without returning in sinus rhythm);
• development of heart failure symptoms;
• drug refractoriness or intolerance (two or more drugs, including amiodarone);
• need for frequent electrical cardioversions (> 1 in the previous year);
• high probability after the procedure to remain in sinus rhythm for a reasonable period of time.

The last point is the most difficult to be defined. Heart failure, valvular heart disease, left atrial dysfunction as well as prior repetitive cardioversion with short-term recurrence of the arrhythmia should identify the patients with low probability of remaining in sinus rhythm. As a matter of fact, no conclusive data are available in this field.

From the psychological point of view, the "ideal patient" should be an active person, without any significant past/present psychological distress (i.e. depression or high anxiety), able to understand his disease and the device with its risks and benefits. He should be ready to accept a device that shocks him for a non-life-threatening condition.

Recommendations in the atrial defibrillator setting

As far as shock delivery mode is concerned, three options are available:
• patient activator should be preferred for younger and still active people who wish to keep control of their symptoms and their lives; usually they also have a strong family support. Some of them may ask for light sedation during shock delivery. The risk is not to treat asymptomatic atrial fibrillation episodes, if any;
• in hospital manually delivered shock should be considered for patients who prefer to be shocked by the physician and supported by the care team. They are usually older and uncomfortable in shocking themselves. The risk is not to treat asymptomatic atrial fibrillation episodes and to delay the treatment of very symptomatic episodes;
• automatic shock (at night or at any time with or without a programmable delay from arrhythmia onset) should be preferred when atrial fibrillation leads to major hemodynamic complications, such as acute heart failure or myocardial ischemia. Nocturnal shock should be preferred when arrhythmia tolerance is acceptable and a delay in final therapy does not impair clinical status. It has been reported that nocturnal shock may be better tolerated because it does not interrupt any activity and pain feeling is reduced while the patient is sleeping. Anyway, it should not be programmed in highly anxious patients because it could induce sleep disturbances. The greatest benefit of nocturnal shock is the capability of treating all the episodes (symptomatic and asymptomatic) within 24 hours of the onset, so increasing the time in sinus rhythm and preventing electrophysiological remodeling. While programming an automatic shock, it should not be forgotten that unpredictability of shock delivery may be the main cause of fear and anxiety[11].

In any case, individual tailoring is to be considered the best way for increased therapy acceptance. Good understanding of the disease and awareness of the ben-

efits expected from device implantation, such as symptom control and reduction of drugs and hospitalizations, may increase patient compliance.

Perspectives

In spite of documented benefits of physiological pacing in atrial fibrillation prevention in patients with sinus node disease[12], atrial fibrillation is still a common event during the follow-up of this patient population after implantation. In the Canadian Trial of Physiologic Pacing[13] the annual risk of developing atrial fibrillation was 5.66% and prior atrial fibrillation was associated with an annual risk of 9.64%. In the Mode Selection Trial in Sinus-Node Dysfunction[14], after a median follow-up of 33 months, 21.4% of patients in the dual-chamber pacing arm had atrial fibrillation and chronic atrial fibrillation occurred in 15.2%.

The introduction of sophisticated pacing algorithms aimed to prevent and early treat atrial fibrillation as well as atrial cardioversion facilities in new multifunction devices may represent the new frontier for atrial fibrillation treatment. Such a device may be capable of offering a full-option treatment for patients with atrial fibrillation and bradycardia indication for pacing. Early cardioversion of atrial fibrillation may reduce hospitalizations and health care consumption and may improve quality of life. Reduction of health care consumption may overbalance the increased device costs.

Clinical studies in this field will be welcome in order to define optimal patient selection and careful cost-benefit analysis.

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