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Multicenter Low Energy Transvenous Atrial Defibrillation (XAD) Trial Results in Different Subsets of Atrial Fibrillation

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Objectives. **This prospective, multicenter trial was aimed at defining efficacy and safety of low energy shocks during atrial fibrillation in a diverse cohort of patients.**

Background. **Experimental studies in sheep and preliminary data in humans have suggested that low energy internal shocks delivered between right atrial and coronary sinus electrode catheters may terminate atrial fibrillation.**

Methods. **Biphasic 3/3-ms R wave synchronous shocks were delivered between two electrode catheters in the right atrium and coronary sinus. The defibrillation protocol started with a test shock of 20 V, and shocks increased in 40-V steps until restoration of sinus rhythm or a maximum of 400 V. Shock delivery was withheld after short RR intervals. In 141 patients with atrial fibrillation, the protocol was carried out under sedation in case the shock was associated with discomfort. The atrial arrhythmia was paroxysmal (≤7 days) in 50 patients, chronic (>30 days) in 53, intermediate (>7 days, ≤30 days) in 18 and induced in 20. Underlying heart disease was present in 88 patients (62%).**

Results. **Paroxysmal atrial fibrillation was successfully terminated in 46 (92%) of 50 patients, chronic atrial fibrillation in 37 (70%) of 53, intermediate in 16 (89%) of 18 and induced in 16 (80%) of 20. Mean conversion threshold was 1.8 J (213 V) in the induced group, 2.0 J (229 V) in the paroxysmal group, 2.8 J (272 V) in the intermediate group and 3.6 J (311 V) in the chronic group. The conversion voltage was significantly ($p < 0.001$) higher in the chronic group than in the other groups of atrial fibrillation and increased significantly with the duration of atrial fibrillation and with left atrial size ($p < 0.05$). Of 1,779 R wave synchronized shocks delivered with a mean (±SD) preceding RR interval of 676 ± 149 ms, no ventricular arrhythmia was induced. The latter may occur after unsynchronized shocks.**

Conclusions. **Low energy transvenous shocks in patients with atrial fibrillation are effective and safe, provided that shocks are properly synchronized to R waves with preceding RR intervals that meet appropriate cycle length criteria. This study provides data that may be useful in the development of an implanted atrial defibrillator.**

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Atrial fibrillation, an extremely common arrhythmia, is estimated to occur in 2% to 4% of the general population >65 years old (1). The incidence is even higher in patients with underlying heart disease. Atrial fibrillation may be associated with symptoms, hemodynamic impairment of cardiac function and an increased risk of cerebrovascular and systemic thromboembolism (2). Antiarrhythmic drug therapy is widely prescribed to prevent recurrence of atrial fibrillation. As pointed out by Antman et al. (3), the benefits of treatment with conventional antiarrhythmic agents have not been demonstrated in large-scale, randomized clinical trials. Although newer antiarrhythmic agents, such as propafenone, flecainide or sotalol, seem to be associated with a relatively low incidence of side effects, the long-term safety of these antiarrhythmic agents remains to be evaluated (3). Conversion to sinus rhythm represents the ideal end point of therapy for patients with persistent, non–self-terminating atrial fibrillation because it should restore both normal hemodynamic function and a slower heart rate. Restoring sinus rhythm may eliminate symptoms, reduce thromboembolic complications, improve exercise capacity and most likely improve survival. Recent observations reported by Wijffels et al. (4) suggest that atrial fibrillation may cause electrophysiologic changes of the atrial myocardium that favor the perpetuation of atrial fibrillation. In their goat model of atrial fibrillation, the increase in duration of the arrhythmia was associated with a shortening of the atrial effective refractory period. Therefore, prompt termination of

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atrial fibrillation is desirable before these changes take place or become irreversible.

Introduced 30 years ago and popularized by Lown (5), external electrical cardioversion is an effective and safe treatment for restoring sinus rhythm. Internal cardioversion was shown to be an alternative therapy in patients with failed external cardioversion (6,7). Both techniques require high energy shocks and general anesthesia. After the report of Cooper et al. (8) showing that pacing-induced atrial fibrillation in sheep may be successfully cardioverted with low energy shocks delivered between the right atrium and the coronary sinus, there have been isolated attempts to terminate atrial fibrillation in humans. However, limited data are available on the efficacy of low energy internal cardioversion in patients with long-standing atrial fibrillation (9,10) and no data on diverse populations of patients.

The objective of the present prospective, multicenter study was to evaluate the efficacy and safety of biphasic shocks applied between right atrial and coronary sinus electrode catheters in different subsets of patients with atrial fibrillation. A previous report (10) described the feasibility of low energy shocks in 19 patients with induced atrial fibrillation. The present report provides the data for 141 patients and includes patients with spontaneous as well as induced atrial fibrillation.

Methods

Study patients. This prospective study included six centers: Queen Mary Hospital in Hong Kong, St. George's Hospital in London, University of Ghent in Ghent, Centre Hospitalier Universitaire Vaudois in Lausanne, OLV Hospital in Aalst and Centre Hospitalier et Universitaire Hôpital Nord in Marseille. Entry criteria included 1) age >18 years; 2) an indication for cardioversion, including patients with failed external cardioversion and those with atrial fibrillation induced in the electrophysiologic laboratory in the course of another study; 3) written informed consent obtained; 4) adequate oral anticoagulation with warfarin or a similar agent, for a minimum of 3 weeks or subcutaneous or intravenous heparin for a minimum of 3 days and absence of thrombus on the transesophageal echocardiogram. Patients were excluded from the study if one or more of the following conditions were present: 1) history of cerebrovascular accident; 2) atrial fibrillation resulting from an acute or subacute illness or uncontrolled congestive heart failure; 3) ejection fraction <20%; 4) patients with documented or suspected thrombus in the left atrial or ventricular chambers. Patients with atrial fibrillation were classified into four groups: paroxysmal, chronic, intermediate and induced. *Paroxysmal atrial fibrillation* was defined as attacks of arrhythmia lasting <7 days and separated by periods of normal sinus rhythm. *Chronic atrial fibrillation* was defined as atrial fibrillation lasting >30 days. Atrial fibrillation was said to be *intermediate* if it lasted >7 days and ≤30 days. *Induced atrial fibrillation* was atrial fibrillation occurring in the course of an electrophysiologic study and mechanically or electrically induced. Whenever appropriate, antiarrhythmic therapy was discontinued for 5 half-lives. However, the presence of antiarrhythmic therapy was not an exclusion criterion. All patients underwent a workup, including history and physical examination, 12-lead electrocardiography, chest radiography, 24-h ambulatory monitoring, M-mode and two-dimensional echocardiography, laboratory tests (creatinine, serum potassium, red blood count) and thyroid function evaluation. The protocol received approval from the ethical committee of each participating center.

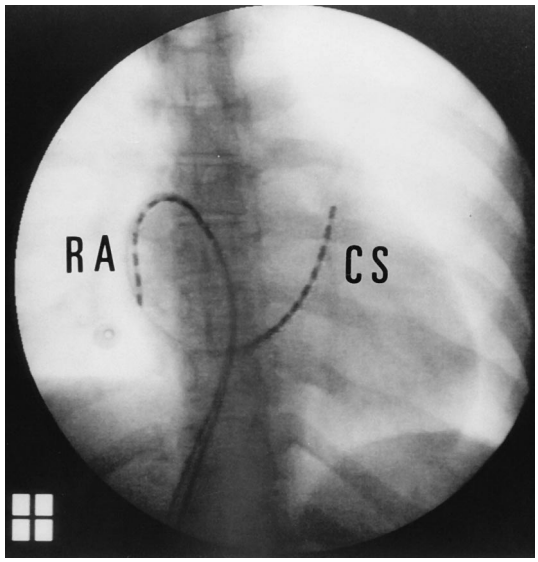


Figure 1. Electrode configuration. Anteroposterior chest radiograph showing an electrode catheter in right atrium (RA) and coronary sinus (CS).

Protocol design. The protocol consisted of biphasic 3/3-ms shocks (Fig. 1) delivered from a custom external atrial defibrillator having a single 80-μF capacitor and a maximal output of 400 V (XAD InControl Inc.). Shocks were delivered through two 6F temporary electrode catheters with nine poles of ~2.8-cm^2 surface area each (Elecath). One electrode was positioned in the right atrium such that the electrodes had contact with the anterolateral wall. The other electrode was positioned in the coronary sinus. The right atrial catheter served as the cathode and the coronary sinus catheter as the anode. The external atrial defibrillator allowed the user to program leading-edge voltage and minimal RR interval, after which a shock could be delivered. After each shock, the defibrillator depicted the voltage, energy and impedance. R wave synchronization signals were obtained from electrophysiologic laboratory monitors and achieved through a variety of external synchronization systems, not usually with an implanted ventricular lead. Cardioversion was performed under local anesthesia, in the fasting state, and, whenever needed, conscious sedation was provided. The defibrillation protocol included a single conversion and an initial test shock of 20 V; the energy was then increased in 40-V steps until restoration of sinus rhythm or a maximum of 400 V. One shock was given at each voltage level, and shocks were withheld after short RR intervals (<300 ms). Whenever possible, the RR interval

Table 1. Clinical Characteristics of 141 Patients

	Paroxysmal AF Group (n = 50)	Chronic AF Group (n = 53)	Intermediate AF Group (n = 18)	Induced AF Group (n = 20)
Age (yr)	58 ± 12	58 ± 11	69 ± 14	49 ± 11
M/F	40/10	42/11	10/8	11/9
BSA (m^2)	1.91 ± 0.21	1.88 ± 0.20	1.75 ± 0.24	1.72 ± 0.23
AF duration (days)	1.27 ± 1.92	458 ± 568	17.2 ± 6.7	NA
LA diameter (mm)	38 ± 8	45 ± 87	42 ± 5	36 ± 5
Heart disease present/absent	22/28	19/34	8/10	5/15
Antiarrhythmic agents	18	8	6	4

Data presented are mean value ± SD or number of patients. AF = atrial fibrillation; BSA = body surface area; F = female; LA = left atrial; M = male; NA = not applicable.

preceding shock was set at ≥500 ms. It was recommended that, after restoration of sinus rhythm, oral anticoagulation be prescribed for a minimum of 1 month.

Statistical analysis. All statistic analyses were performed using Statview 4.5. Regression tests were done by both multiple and stepwise regression. Creatine kinase analysis was done by analysis of variance (ANOVA). Differences between groups were analyzed by unpaired *t* test after analysis of variance, and, when needed, nonparametric tests were performed. For left atrial size, the Fisher test was used for comparison between groups.

Results

Clinical characteristics of patients. A total of 153 patients were eligible for the trial, 12 of whom were excluded from cardioversion analysis because the primary rhythm was flutter in 2, and the left-sided lead was placed in the pulmonary artery in 10 because the coronary sinus could not be catheterized. One hundred forty-one patients (103 men, 38 women; mean [±SD] age 58 ± 13 years, range 18 to 87) were therefore enrolled in the trial. Structural heart disease was detected in 54 patients (38%) and included hypertension in 21, cardiomyopathy in 10, valvular heart disease in 15, coronary artery disease in 6 and congenital abnormality in 5. No heart disease was reported in 87 patients (62%). Fifty patients (35%) were classified as having paroxysmal, 53 (37%) chronic, 18 (13%) intermediate and 20 (14%) induced atrial fibrillation. The clinical characteristics of the four groups of patients are shown in Table 1. The mean age of all groups together was significantly different from that of each individual group ($p < 0.01$), except for the chronic and paroxysmal groups whose mean ages were similar. Body surface area was significantly different in the induced group compared with the chronic or paroxysmal groups. Left atrial diameter was significantly different in the chronic (44 ± 7 mm) versus the induced group (35 ± 5 mm), the chronic versus the paroxysmal (39 ± 7 mm) group and the intermediate (42 ± 5 mm) versus the induced group.

Response to transvenous cardioversion. In response to the defibrillation protocol, 115 (82%) of the 141 patients had restoration of sinus rhythm with a mean of 12.4 shocks/patient (range 3 to 38). An example of successful termination of atrial fibrillation using a low energy shock is shown in Figure 2. As shown in Table 2, paroxysmal atrial fibrillation was terminated in 46 (92%) of 50 patients with a mean conversion voltage of 229 V and a mean conversion energy of 2.0 J (range 0.3 to 4.4). Chronic atrial fibrillation was terminated in 37 of 50 patients with a mean conversion voltage of 311 ± 60 V and a mean conversion energy of 3.6 J (range 0.6 to 6.2). Intermediate atrial fibrillation was reverted to sinus rhythm in 16 (89%) of 18 patients with a mean conversion voltage of 272 V and a mean conversion energy of 2.8 J (range 1.1 to 4.4). In the induced atrial fibrillation group, sinus rhythm was restored in 16 of 20 patients with a mean conversion voltage of 213 V and a mean energy of 1.8 J (range 0.3 to 4.3). The defibrillation impedance, calculated as the mean of the impedances measured after each shock and for each patient, did not show any significant difference between the four groups of patients.

Safety. A total of 1,779 shocks were delivered to the 141 patients, with a mean preceding RR interval of 676 ± 149 ms (Table 3). No complications were observed after R wave synchronized shocks. Creatine kinase enzyme levels measured before (80 ± 52 IU), immediately after (82 ± 49 IU) and 2 and 6 h after reversion to sinus rhythm (89 ± 59 and 90 ± 66 IU,

Figure 2. Successful termination of atrial fibrillation after low energy transvenous cardioversion. The leading edge voltage was 260 V and the energy 2.6 J. Note that in this case the proper synchronization signal (S) was obtained from the surface electrocardiogram.

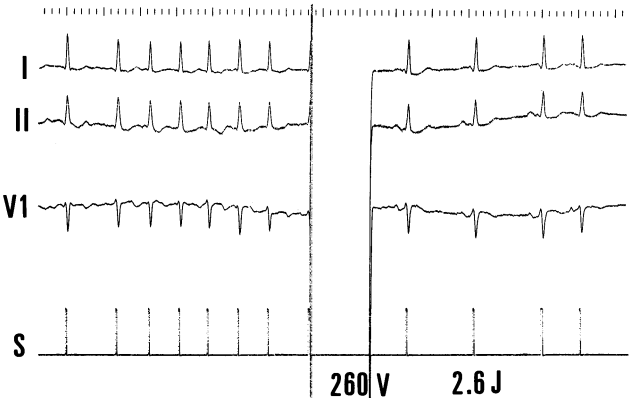


Table 2. Results of Transvenous Low Energy Cardioversion in 141 Patients Included in Multicenter Trial

AF Group	Success	Shock (V)	Conversion Threshold (J)	Impedance (ohms)	Previous RR Interval (ms)
Paroxysmal (n = 50)	46 (92%)	229 ± 55 (100–340)	2.0 ± 0.97 (0.3–4.4)	58 ± 9 (38–83)	657 ± 145 (372–982)
Chronic (n = 53)	37 (70%)	311 ± 60 (140–400)	3.6 ± 1.4 (0.6–6.2)	65 ± 10 (44–85)	653 ± 124 (500–975)
Intermediate (n = 18)	16 (89%)	272 ± 56 (180–340)	2.8 ± 1.0 (1.1–4.4)	58 ± 10 (38–78)	668 ± 107 (500–911)
Induced (n = 20)	16 (80%)	213 ± 73 (100–340)	1.8 ± 1.3 (0.3–4.3)	63 ± 11 (49–83)	658 ± 189 (312–964)

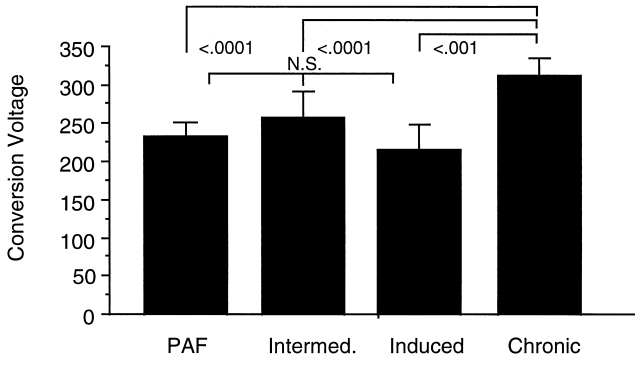
Data presented are number (%) of patients or mean value ± SD (range). AF = atrial fibrillation.

respectively) or completion of the defibrillation protocol, did not show any significant increase. No other evidence of cardiac injury including monitoring of the electrocardiogram after shocks, was seen during the study.

Sedation. Of 141 patients, 50 received sedation at the start of the study, and 91 were not sedated. Of these 91 patients, sedation was needed at some point in 53 because of patient discomfort.

Variables affecting the results. When variables that may affect conversion voltage were examined, type of atrial fibrillation, duration of atrial fibrillation and size of the left atrium were significant. The conversion voltage required to terminate atrial fibrillation in the chronic group was significantly higher than that in the paroxysmal or the induced group ($p < 0.001$) (Fig. 3). There was no significant difference in successful conversion voltage in the chronic group between patients with atrial fibrillation established <90 days (11 patients) and those with atrial fibrillation established >3 months. There was a significant relation between conversion voltage and duration of atrial fibrillation or left atrial diameter ($p < 0.05$). However, the correlation coefficients for these two variables were low. The variables that were found not significantly related to conversion voltage were age, height, weight, previous RR interval and body surface area.

Figure 3. Conversion voltage and type of atrial fibrillation. Chronic atrial fibrillation required significantly higher conversion voltages than other types of atrial fibrillation. Intermed. = intermediate; PAF = paroxysmal atrial fibrillation.



Although reproducibility was not tested in this study, three patients underwent repeat cardioversion after attaining sinus rhythm. The mean conversion energy changed from 5.8 to 2.5 J.

Discussion

Background. Synchronized electrical cardioversion remains the most successful and the safest treatment for reestablishing sinus rhythm in patients with atrial fibrillation (5,12). It is commonly achieved using anterolateral paddle placement or anteroposterior paddle placement on the thorax and delivering ≥100-J shocks under general anesthesia. Although the overall success of external cardioversion is reported to be high (5), this technique may fail in a number of patients (7). Among the factors likely to affect the results, transthoracic impedance, energy level and paddle position have been implicated (13,14). Lévy et al. (6) reported successful cardioversion of chronic atrial fibrillation using shocks delivered between an electrode catheter in the right atrium (cathode) and a back plate (anode) in patients with failed external cardioversion. This technique used energy of 200 or 300 J under general anesthesia. Previous attempts to terminate atrial fibrillation by delivering intracardiac shocks in the right atrium with low energies have been disappointing. Dunbar et al. (15) achieved termination of only 26% of episodes of atrial fibrillation with energies <5 J in a model of talc-induced pericarditis in dogs. Nathan et al. (16), using a similar technique, were unsuccessful in terminating atrial fibrillation in patients. Both studies used a catheter (Medtronic 6880) with the anode and cathode on the same catheter. A different approach was taken by Kumagai et al. (17), who used a technique in dogs comparable to that used by Lévy et al. (6) and were able to successfully terminate atrial fibrillation with monophasic shocks of 1 J in 70% of attempts. Cooper et al. (8) found that in an experimental model of pacing-induced atrial fibrillation in sheep, the electrode configuration that resulted in the lowest energy requirement comprised catheters in the right atrial appendage and coronary sinus. In their studies, biphasic shocks resulted in the lowest defibrillation energy requirements of the waveforms tested.

These findings prompted the present multicenter trial aimed at evaluating the safety and efficacy of biphasic shocks delivered between the right atrium and coronary sinus electrode catheters in patients with atrial fibrillation.

Comparison with previous reports. The present study showed that it was possible to terminate atrial fibrillation in different subsets of patients with ≥75% success with a mean energy ranging from 0.3 to 6.2 J. Alt et al. (9) were successful in reestablishing sinus rhythm in 10 of 13 patients with chronic atrial fibrillation with a mean energy of 3.7 ± 1.7 J. Murgatroyd et al. (11) were able to terminate pacing or mechanically induced atrial fibrillation in 19 patients, with an energy ranging from 0.7 to 4.4 J. Only four of their patients had spontaneous atrial fibrillation. These patients are also part of the present study. Saksena et al. (10) found high defibrillation thresholds using different electrode configurations, in particular, a right atrium to axillary patch electrode (20.1 ± 7.4 J). The best lead configuration resulted in a mean defibrillation threshold of 9.9 ± 7.7 J. The present conversion data in 141 patients are consistent with previous reports using a right atrium to coronary sinus vector and show that regardless of the type of atrial fibrillation, successful termination may be obtained using low energy shocks. Furthermore, the study showed that the conversion voltage required for restoring sinus rhythm in patients with chronic atrial fibrillation is higher than that required for other types (i.e., paroxysmal, intermediate or induced) of atrial fibrillation.

Safety. In this study, no complications occurred after 1,779 R wave synchronized shocks. It should be emphasized that according to the defibrillation protocol, shocks were generally withheld after short RR intervals (<500 ms). The latter was based on the experimental work of Ayers et al. (18) who showed that synchronized shocks delivered after short RR intervals (<300 ms) were associated with an increased risk of induction of rapid ventricular tachycardia or fibrillation. Murgatroyd et al. (19) compiled the experience of a number of different centers evaluating transvenous low energy atrial fibrillation and observed no ventricular tachyarrhythmias in a total of 1,212 shocks. The mean preceding RR interval was 619 ± 214 ms, similar to that of 676 ± 149 ms found in the present trial. However, they observed transient bradycardia and occasional pauses (≤6,280 ms), suggesting that synchronized shocks delivered by an implanted atrial defibrillator would require antibradycardia support pacing. The cases analyzed by Murgatroyd et al. (19) included only the partial experience of two of the centers that participated in the present study. We observed a ventricular proarrhythmia in a patient with flutter after an unsynchronized shock due to a faulty synchronization on the T wave. Ventricular tachycardia rapidly degenerating into ventricular fibrillation occurred. Sinus rhythm was restored after prompt external cardioversion. A similar case was reported by Falk and Podrid (12) after an attempted external cardioversion of atrial flutter and improper synchronization, resulting in a delivered shock on the T wave and ventricular fibrillation. Saksena et al. (11) observed nonsustained polymorphic ventricular tachycardia after a poorly synchronized shock, also in a patient with flutter. Although rare, the possibility of such a serious event emphasizes the importance of R wave synchronization, hence requiring a lead placed in the right ventricle for an implanted atrial defibrillator.

Clinical applications. Low energy transvenous cardioversion has a number of clinical applications that may be classified into two types:

1. Cardioversion using an external device and temporary electrode catheters may have a number of potential applications. It may be used to terminate pacing or catheter-induced atrial fibrillation complicating an electrophysiologic study. Low energy transvenous cardioversion does not require general anesthesia, and only mild sedation using midazolam may be needed. This technique may be used to repeatedly terminate recurrent atrial fibrillation in intensive care units, particularly after open heart surgery. High energy internal cardioversion has been suggested as an option in patients with failed external cardioversion (6,7,20,21). Low energy cardioversion may be an alternative in patients with high transthoracic impedance, such as obese patients or patients with chronic obstructive lung disease.

2. Low energy cardioversion may have an application in implanted devices. In the ventricular implantable cardioverter-defibrillators, atrial fibrillation is often responsible for inappropriate shocks. The latter may even be responsible for ventricular proarrhythmia. Proper detection and termination of atrial fibrillation may be a useful addition to currently available implantable cardioverter-defibrillators in patients with malignant ventricular arrhythmias. Moreover, our results on the safety and efficacy of low energy transvenous cardioversion support the feasibility of an implanted atrial defibrillator. Such a device may widen the scope of nonpharmacologic therapy of atrial fibrillation and may be an alternative therapy to ablation of the atrioventricular node and pacemaker implantation. The efficacy of low energy cardioversion demonstrated in this study indicates that there may be a subgroup of patients with atrial fibrillation who may benefit from an implanted atrial defibrillator, provided that the safety and tolerability of such device are proved by appropriately conducted clinical trials. In three patients who required repeated cardioversion, the mean conversion energy was lower, which suggests that periods of sinus rhythm may induce remodeling of the atria. More data are needed to support such hypothesis in patients.

Study limitations. Although the present report provides information on the safety and feasibility of low energy transvenous cardioversion of atrial fibrillation, it does not address a number of issues. As pointed out by Murgatroyd et al. (10), the energy required to restore sinus rhythm with the defibrillation protocol used does not represent a defibrillation threshold. Cardioversion may result from a cumulative energy due to previous ineffective shocks. The same limitation applies to the so-called ventricular defibrillation threshold. The protocol of this trial was not intended to test the reproducibility after a successful shock. Although the protocol included the evaluation of shock-related discomfort, it appeared difficult to

present meaningful data for a number of reasons. The type and time at which sedation should be used were left to the judgment of the investigator and to the consent obtained from the patient to undergo the protocol without sedation. In the Marseille experience, only 30 of 42 patients agreed to undergo the protocol without sedation. In contrast, it would be inappropriate to lump together the data on pain from five countries over two continents using a subjective scale because the perception of pain may well be cultural. The issue of pain should be evaluated separately in a specially designed protocol.

Conclusions. This prospective, multicenter trial on low energy transvenous cardioversion of atrial fibrillation showed, in a total of 141 patients, that shocks delivered between two electrode catheters in the right atrium and coronary sinus are effective in restoring sinus rhythm. This technique is safe, provided that shocks are synchronized to the R wave with preceding RR intervals that meet appropriate cycle length criteria. Unsynchronized shocks present the risk of ventricular proarrhythmia. Although the technique was successful in restoring sinus rhythm in 82% of patients, the conversion voltage required was significantly higher in patients with chronic atrial fibrillation than those with other types of atrial fibrillation and increased with the duration of atrial fibrillation and left atrial size. The procedure does not require general anesthesia and may be useful in terminating persistent atrial fibrillation in a number of clinical situations. This study provides important data pertinent to the potential use of an implanted atrial defibrillator.

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