Low energy intracardiac cardioversion of chronic atrial fibrillation by single femoral approach: safety and effectiveness of the procedure

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Atrial fibrillation; Cardioversion.

Background. **Low energy intracardiac cardioversion has recently been introduced into clinical practice to treat both acute and chronic atrial fibrillation. It has also been suggested that low energy intracardiac cardioversion has a higher efficacy rate in restoring sinus rhythm than conventional external cardioversion.**

Methods. **A prospective study was started in 41 patients (mean age 64.5 years) with chronic atrial fibrillation (mean duration 6.5 months), in order to obtain more data on low energy intracardiac cardioversion concerning: 1) time required to perform low energy intracardiac cardioversion by single venous femoral approach; 2) acute efficacy; 3) incidence of complications; 4) persistence of sinus rhythm after 1 month.**

Results. **Twenty patients had right atrium-coronary sinus (Group A) and 20 right atrium-left pulmonary artery (Group B) electrode configuration for defibrillation. In 1 patient the configuration was not available. In all patients (100%) sinus rhythm was acutely restored. No statistically significant differences were found between the two groups concerning mean energy and impedance required to obtain cardioversion. With mild sedation the discomfort induced by the electrical shock was minimal or mild. Only 44% of patients were in sinus rhythm 1 month after low energy intracardiac cardioversion, in spite of adequate pharmacological therapy.**

Conclusions. **Low energy intracardiac cardioversion by single venous femoral approach may be considered a very effective and not time consuming procedure in acutely restoring sinus rhythm, with low complication rate; in addition the procedure was well accepted by all patients.**

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Low energy intracardiac cardioversion has recently been introduced into clinical practice to treat both acute and chronic atrial fibrillation[1-10]. It has also been suggested that low energy intracardiac cardioversion has a higher efficacy rate in restoring sinus rhythm than conventional external cardioversion[11-14].

Presently, however, external cardioversion is the first choice approach in the treatment of atrial fibrillation in emergency or elective cases, when pharmacological cardioversion is not indicated or has failed to restore sinus rhythm.

Definite guidelines for application of low energy intracardiac cardioversion are not currently available although the use of this procedure has generally been indicated: 1) in cases of external cardioversion failure; 2) when general anesthesia should be avoided or is contraindicated; 3) when low energy intracardiac cardioversion is preferred by the patient; or 4) when atrial fibrillation occurs during electrophysiological study. Not widely accepted but emerging indications are obesity and severe chronic lung diseases. Several authors agree that low energy intracardiac cardioversion is effective, safe and well tolerated[10,15-22]. Indications for its use may be extended if it could be demonstrated that the method is simple, effective, not time consuming, and not very expensive.

To our knowledge there is little information in the literature concerning the time required to perform the procedure and the degree of its acceptance by the patient. On the other hand, a factor that could reduce the

widespread use of low energy intracardiac cardioversion is the potential technical difficulty of its performance.

Usually, to perform low energy intracardiac cardioversion, a first catheter is positioned into the right atrium (RA), a second one into the left branch of the pulmonary artery (LPA) or in the distal part of the coronary sinus (CS). A third catheter is placed at the apex of the right ventricle in order to synchronize the electric shock with ventricular depolarization and to allow backup pacing (Fig. 1). For CS position, a second venous access site is usually required, i.e. through the subclavian or internal jugular vein[6,11,13,23,24]. This additional venous access site, however, can increase the risk of complications, like hemorrhage, hematoma or infection. The additional venous puncture is time consuming and may produce further discomfort to the patient.

For these reasons we started a prospective study to evaluate: 1) the time needed to perform low energy intracardiac cardioversion; 2) the acute efficacy of the procedure in restoring sinus rhythm; 3) the incidence of complications using the femoral venous access site; and 4) the persistence of sinus rhythm after 1 month of follow-up.

Methods

Our study group consisted of 41 consecutive patients (25 males and 16 females, mean age 64.5 years, range 41-76 years) who underwent low energy intracardiac cardioversion. Twenty-one patients had systemic hypertension, 3 ischemic heart disease, 3 dilated cardiomyopathy, 6 mitral valve disease, while 8 patients had no other signs of cardiac pathology except for atrial fibrillation (lone atrial fibrillation) (Table I). Patients were enrolled into the study if they met the following criteria: 1) minimum duration of chronic atrial fibrillation (as documented by 12-lead ECG) had to be at least of 1 month (mean 6.5 months, range 1-96 months); 2) patients gave informed consent to low energy intracardiac cardioversion as the preferred choice, or as the alternative procedure to conventional external cardioversion.

Table I. Underly ing heart disease.

Heart disease	No. patients
Systemic hypertension	21
Ischemic heart disease	3
Dilated cardiomyopathy	3
Mitral valve disease	6
No heart disease	8

The patients were instructed to withdraw from oral therapy (antiarrhythmics, digitalis, or beta-blockers) at least 48 hours before the procedure. Only amiodarone was allowed (15 patients were on chronic amiodarone).

To try to avoid uncertainties and bias in the interpretation of the results the antiarrhythmic drugs were discontinued.

Each patient had to be correctly anticoagulated with INR values between 2 and 3 at least for 1 month before the procedure. Anticoagulation was discontinued the day before the procedure only if INR was > 2.5. However, no patient was rejected at the time of the procedure for INR reasons. Anticoagulation therapy was usually restarted the evening after the procedure and maintained in therapeutic range for at least another month.

Low energy intracardiac cardioversion procedure consisted of few sequential actions. A local anesthetic with lidocaine 2% was performed at the right inguinal area. A standard tetra or bipolar catheter was inserted via the right femoral vein into the apex of the right ventricle in order to synchronize the electric shock with ventricular depolarization and for backup pacing. At the same site two 8 F large surface area electrodes (Trans-

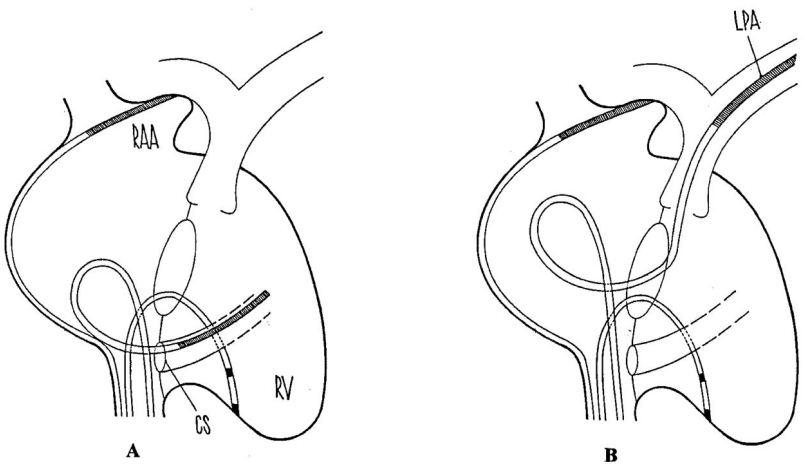

Figure 1. *Electrode configurations in Group A and Group B.* A: *right atrium-coronary sinus configuration (Group A).* B: *right atrium-left pulmonary artery configuration (Group B). CS = coronary sinus; LPA = left pulmonary artery; RAA = right atrium appendage; RV = right ventricle.*

vene 6933-110 or indifferently Transvene 6937-110, Medtronic Inc., Minneapolis, MN, USA), were also inserted to perform cardioversion. These two leads were positioned into two different sites: the first one in the upper RA with the tip located into the appendage, and the shaft along the lateral wall; the second one was positioned, without having been predetermined, either into the CS (Group A) or the LPA (Group B) (Fig. 1). Usually the same venous access was used for the right ventricular lead and for the RA defibrillation lead. A second venous access site through the same femoral vein was used for the second defibrillation catheter to achieve easier manipulation.

Energy was delivered from a defibrillator support device Medtronic model DISD 5358 that allowed selection of designated energy levels and also displayed circuit impedance and actual delivered energy for each discharge. Biphasic truncated 65% tilt asymmetric pulses were delivered. After an initial shock at 0.2 J for impedance test, subsequent shocks were discharged in sequence with increasing programmed energy from 8-10-13-15-20 J. The procedure was stopped as soon as sinus rhythm or maximal programmed energy was reached.

The total procedure duration time was calculated from the beginning of preparation of the sterile field to the time when all catheters were removed and the access site was securely clotted. The time needed from the inguinal puncture to the time when all three catheters were considered correctly in place was also calculated, and so was the time from when the catheters were in place to the last shock. Finally the fluoroscopic time needed to perform the procedure was measured.

The same cardiologist with adequate hemodynamic and electrophysiological expertise with the support of a trained registered nurse and a medical technician performed all procedures.

At the beginning of the procedure, a mild sedation with diazepam was given; the drug could be repeated during the procedure, depending on the anxiety of the patient and his acceptance of the procedure. Five minutes prior to the first shock, each patient received propafenone (1.5 mg/kg i.v.). As soon as sinus rhythm was restored an intravenous infusion of propafenone with a fixed dose of 70 mg was started and completed in 1 hour. Propafenone treatment was used to further prevent early recurrence of atrial fibrillation.

Before the procedure, each patient had a blood sample test to obtain serum levels of creatine phosphokinase (CPK), CPK-MB, white blood cells, INR, and potassium.

In all patients the samples for CPK, CPK-MB and white blood cells were obtained again 16-20 hours after the end of the procedure.

The ECG was monitored until the patient was discharged, usually after 4-6 hours from the removal of the catheters. At that time, the patient underwent a final 12-lead ECG. A conventional 12-lead ECG was also obtained the next day, 7 days later and 1 month later to verify the persistence of sinus rhythm.

Before discharge, the patient was asked to describe the level of discomfort caused by the intrathoracic shock using a four grade scale: grade 1 = minimal or no discomfort, grade 2 = mild, grade 3 = moderate, grade 4 = severe discomfort. The level of discomfort was graded at discharge to avoid influence by the sedation at the end of the procedure.

Patients who previously experienced external cardioversion, were also asked to indicate the procedure of preference.

Statistical analysis. Continuous variables were compared using the unpaired Student's t test and values expressed as mean ± SD or percentages.

Results

A successful cardioversion was achieved in all patients (100%). The mean number of shocks attempted for each patient was 2.4 (range 1-5). In 15 patients (36.6%) sinus rhythm was restored at the first attempt with set energy of 8 J, in 6 patients (14.6%) at the second at 10 J, in 11 patients (26.8%) at the third at 13 J, in 8 patients (19.5%) at the fourth at 15 J, and in 1 patient (2.5%) at the fifth attempt at 20 J.

The mean energy required was 10.3 J (range 7.2-20.7 J). The mean impedance at the maximum energy delivered was 55.7 Ohms (range 32-80 Ohms).

The Group A configuration (RA-CS) was used in 20 patients with mean energy required to restore sinus rhythm of 10.1 ± 3.0 J (range 7.4-13.9 J), with a mean impedance of 50.9 ± 10.1 Ohms (range 35-72 Ohms). The mean number of attempts to restore sinus rhythm was 2.3 ± 1.3 shocks for a total of 47 shocks. In 8 cases (40%) only one shock was needed to achieve sinus rhythm.

The Group B configuration (RA-LPA) was used in 20 patients and required a mean energy of 10.6 ± 3.9 J (range 7.4-20.7 J), with a mean impedance of 57.2 ± 10.2 Ohms (range 44-80 Ohms). The mean number of attempts to restore sinus rhythm was 2.3 ± 1.3 for a total of 46 shocks. In 7 cases (35%) only one shock was necessary.

No parameter reached a statistically significant difference in comparing Group A and Group B (Table II). In one case the lead configuration was not reported.

There were no episodes of ventricular arrhythmias after shock delivery. In 9 cases (22%), ventricular pacing was needed at a programmed rate of 40 b/min. In one case the asystolic pause due to complete heart block lasted 51 s. In the remaining 8 cases ventricular pacing was maintained for a mean time of 5.1 s (range 2-7 s) due to complete heart block in 2 cases and to sinus pause in 6

Table II. Comparative results between Group A and Group B.

Electrode configuration	Total duration of the procedure (min)	Shock energy (J)	Shock impedance (Ohms)	No. shocks
RA-CS (Group A)	41.8 – 11.4	10.1 – 3.0	50.9 – 10.1	2.3 – 1.3
RA-LPA (Group B)	38.5 – 7.9	10.6 – 3.9	57.2 – 10.2	2.3 – 1.3
p =	NS	NS	NS	NS

Values are reported as mean – SD. CS = coronary sinus; LPA = left pulmonary artery; RA = right atrium.

cases.

In 5 cases it was necessary to replace one or both defibrillation catheters due to catheter dislodgment: the protocol was restarted where it was interrupted.

The mean dose of diazepam used during the procedure was 14.5 mg (range 5-25 mg).

The mean duration time required to complete the whole procedure was 40.1 min (range 20-55 min); for electrode positioning 15.2 min (range 5-35 min); between the achieved positioning of the catheters to the last shock 10.8 min (range 5-28 min).

The mean fluoroscopy time to complete the whole procedure was 7.3 min (range 2-17 min).

For the Group A electrode configuration, the mean duration time for the whole procedure was 41.8 ± 11.4 min. The Group B configuration required a mean duration time of 38.5 ± 7.9 min. The time difference between the two configurations was not statistically significant. It should be remembered, however, that the choice of the two configurations was not randomized.

The patients were asked to report their level of discomfort. In patients who achieved sinus rhythm at the first attempt, 4 reported minimal discomfort, 8 mild, 2 moderate, and one severe discomfort. In patients receiving more than one shock, 5 reported minimal discomfort, 15 mild and 6 moderate, none complained of severe discomfort.

The 9 patients who experienced a previous external cardioversion were required to indicate a preference between the two procedures. Five preferred low energy intracardiac cardioversion, 2 external cardioversion, and 2 had no preference.

As far as complications are concerned, hemorrhage at the inguinal puncture site without hematoma was observed in 6 patients. This happened at the time when patients were allowed to sit on the side of the bed or on a chair, usually 4-6 hours after the procedure. In 2 of these patients INR was 1.5. The mean value of INR for the whole population was 2.2.

In one case only, an artero-venous fistula was observed at the level of the femoral vessels; surgical treatment the day after the procedure was required. Other patients reported no complaints after discharge.

None of the patients showed increased levels of serum CPK, CPK-MB or white blood cells during the follow-up. Serum potassium level was in the normal range in all patients.

Clinical follow-up gave the following results: 23 patients (56%) had recurrence of atrial fibrillation at 1 month in spite of adequate pharmacological treatment with amiodarone or propafenone. Of these 23 patients, one showed immediate recurrence of atrial fibrillation after sinus rhythm was achieved and one 3 hours after low energy intracardiac cardioversion; 2 patients had atrial fibrillation the day following low energy intracardiac cardioversion; 14 were found in atrial fibrillation 7 days after the procedure and the remaining 5 were found in atrial fibrillation at 1 month follow-up.

Discussion

Recent literature has shown increased interest in atrial fibrillation due to its large clinical, socio-economic and therapeutic impact. Clinical implications such as stroke, heart failure, angina, and cardiomyopathies are relevant. Social and economic aspects include drug costs, absence from work, and psychological conditioning.

The restoration of sinus rhythm as well as its maintenance is the first end point in the treatment of this kind of arrhythmia.

In recent years, a new method, low energy intracardiac cardioversion, has drawn clinical attention. It has the ability to restore normal sinus rhythm in difficult cases when neither pharmacological nor external cardioversion have shown success. There are however several aspects of the procedure which must be clarified.

In our study group the candidates were patients with chronic atrial fibrillation (> 1 month duration). The acute resolution of the arrhythmia was obtained in all cases. In about one third of the patients the result was obtained with the first shock and, in half of the cases, with a maximum of two shocks. Most patients accepted the procedure without major subjective complaints, defining the discomfort caused by the electrical shock as minimal or mild. The single case in which the electrical shock induced strong discomfort happened in one patient who was not sufficiently informed about the

procedure before delivering the shock. All patients, however, perceived all electrical shocks, including the initial impedance test shock at 0.2 J, independently of the amount of sedation. This is in agreement with some authors[6,16,17,20] but in disagreement with others[18,22]. This confirms the high interpatient variability as far as the subjective tolerance of discomfort is concerned. Most patients who tried both low energy intracardiac cardioversion and external cardioversion, clearly showed a preference for low energy intracardiac cardioversion for different reasons including effectiveness, fear of general anesthesia, and duration of hospital stay. We think that an adequate psychological preparation before the shock and the use of a mild sedation can help to make the procedure more acceptable to patients. In fact the good tolerability of the procedure in our series has been influenced by the sedation strategy.

The complications met were of little clinical significance, except for the single case of artero-venous fistula, which required a surgical approach.

The presence of backup ventricular pacing was helpful in avoiding occasional, prolonged asystolic pauses[25].

The patients were discharged a few hours after the procedure without any major complications. In our experience, the time required to perform the procedure is short. This is greatly due to the flexibility of the approach by using indifferently either the CS or the LPA. The choice of the site is determined by which access of the electrode is the easier.

The unilateral femoral approach allows an acceptable total procedure time, with a low rate of major complications; furthermore it appears to be well tolerated by patients. However, a comparison with other strategies could not be made due to the lack of a control group.

In our study RA-CS electrode configuration did not provide better results as for effectiveness and total duration time of the procedure when compared to RA-LPA configuration. This could be due to the choice of starting with an 8 J shock energy for both configurations. In fact it has been reported in the literature[2] that RA-CS configuration could allow a high success rate with shock energies < 8 J. Our choice, however, was to start with 8 J shock in trying to reduce the number of shocks and make the procedure more tolerable.

Since the distribution of the patients with amiodarone treatment was 30% in RA-CS configuration (Group A) and 45% in RA-LPA configuration (Group B) (p = NS), amiodarone therapy did not seem to influence defibrillation thresholds in our series[8].

The persistence of normal sinus rhythm after low energy intracardiac cardioversion did not give satisfactory results. A short-term recurrence of atrial fibrillation (at 1 month) was observed in over half of the patients even under prophylactic treatment with propafenone or amiodarone. This high percentage, in agreement with other authors[26,27], was probably due to the selection of our patients having long standing atrial fibrillation.

In conclusion, the purpose of this study was not to compare different strategies for cardioversion of atrial fibrillation. However, the results of our study confirm that low energy intracardiac cardioversion is a safe and very effective procedure to restore acutely normal sinus rhythm in chronic atrial fibrillation. For these reasons we believe that the indications for its use could be extended. The single venous femoral approach and unselected RA-CS/LPA catheter configuration allow a short procedure time with good acute effectiveness. The high recurrence rate of atrial fibrillation at 1 month, however, probably suggests the need for a better selection of candidates. Complications were generally of little clinical importance. The discomfort induced by the shock was minimal or mild in most patients.

However our study was not randomized and a control group was not available. Furthermore the problem of the procedure cost/effectiveness ratio has not been defined. We feel moreover that the present approach should not be considered as a first choice in the cardioversion strategies of atrial fibrillation.

We think, however, that the simplified approach to low energy intracardiac cardioversion we have presented, could be of relevance in selected patients due to the safety and effectiveness of the procedure.

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References

1. Alt E, Schmidt C, Ammer R, et al. Initial experience with intracardiac atrial defibrillation in patients with chronic atrial fibrillation. Pacing Clin Electrophysiol 1994; 17: 1067-78.
2. Levy S, Ricard P, Gueunoun M, Trigani J, Saadian A, Paganelli F. Low energy internal cardioversion of spontaneous atrial fibrillation. (abstr) Pacing Clin Electrophysiol 1995; 18: 1120.
3. Levy S, Ricard P, Lau CP, et al. Multicenter low energy transvenous atrial defibrillation (XAD) trial results in different subsets of atrial fibrillation. J Am Coll Cardiol 1997; 29: 750-5.
4. Levy S, Ricard P, Gueunoun M, et al. Low-energy cardioversion of spontaneous atrial fibrillation: immediate and long-term results. Circulation 1997; 96: 253-9.
5. Gasparini G, Bonso A, Rigo F, Raviele A. Acute endocavitary atrial cardioversion: what indications and limitations? In: Raviele A, ed. Cardiac arrhythmias 1997. Milano: Springer-Verlag Italia, 1997: 15-8.
6. Neri R, Palermo P, Cesario AS, Baragli D, Amici E, Gambelli G. Internal cardioversion of chronic atrial fibrillation in patients. Pacing Clin Electrophysiol 1997; 20 (Part I): 2237-42.
7. Murgatroyd FD, Johnson EE, Cooper RA, et al. Safety of low energy transvenous atrial defibrillation. World experience. (abstr) Circulation 1995; 90: I-14.

8. Santini M, Pandozi C, Toscano S, et al. Low energy intracardiac cardioversion of persistent atrial fibrillation. Pacing Clin Electrophysiol 1998; 21: 2641-50.
9. Padeletti L, Porciani MC, Michelucci A. Clinical experience with low energy intracardiac atrial defibrillation. G Ital Cardiol 1998; 28 (Suppl 1): 435-7.
10. Santini M, Pandozi C, Toscano S, et al. Changes in intracardiac atrial cardioversion threshold at rest and during exercise. J Am Coll Cardiol 1997; 29: 576-81.
11. Schmitt C, Alt E, Plewan A, et al. Low energy intracardiac cardioversion after failed conventional external cardioversion of atrial fibrillation. J Am Coll Cardiol 1996; 28: 994-9.
12. Santini M, Pandozi C, Altamura G, et al. Efficacia della cardioversione endocavitaria ad alta e bassa energia nella fibrillazione atriale cronica refrattaria alla cardioversione transtoracica. G Ital Cardiol 1998; 28: 788-96.
13. Sopher SM, Murgatroyd FD, Slade AKB, et al. Low energy transvenous cardioversion of atrial fibrillation resistant to transthoracic shocks. (abstr) Pacing Clin Electrophysiol 1995; 18: 900.
14. Baker BM, Botteron GW, Smith JM. Low energy internal cardioversion for atrial fibrillation resistant to external cardioversion. J Cardiovasc Electrophysiol 1995; 6: 44-7.
15. Jung W, Tebbenjohanns J, Wopert C, Luderitz B. Safety, efficacy and pain perception of internal atrial defibrillation in humans. (abstr) Circulation 1995; 92 (Suppl I): I-492.
16. Steinhaus DM, Cardinal D, Mongeon L, et al. Atrial defibrillation: are low energy shocks acceptable to patients? (abstr) Pacing Clin Electrophysiol 1996; 19: 625.
17. Pandozi C, Gentilucci G, Santini M. Low energy endocavitary cardioversion: safety, effectiveness and tolerability. G Ital Cardiol 1998; 28 (Suppl 1): 437-40.
18. Boriani G, Biffi M, Bronzetti G, et al. Internal low energy cardioversion of atrial fibrillation: patients' tolerance employing a step-up protocol. G Ital Cardiol 1998; 28 (Suppl 1): 433-5.
19. Murgatroyd FD, Slade AKB, Sopher SM, et al. Efficacy and tolerability of transvenous low energy cardioversion of paroxysmal atrial fibrillation in humans. J Am Coll Cardiol 1995; 25: 1347-53.
20. Ammer R, Alt E, Schmitt C, et al. Pain threshold for low energy intracardiac cardioversion of atrial fibrillation with low or no sedation. Pacing Clin Electrophysiol 1997; 20: 230-6.
21. De Simone A, Stabile G, Turco P, Valva G, De Matteis G, Petrazzuoli F. Efficacia e sicurezza della cardioversione interna per il trattamento della fibrillazione atriale di recente insorgenza nel laboratorio di elettrofisiologia. (abstr) G Ital Cardiol 1998; 28 (Suppl 2): 22.
22. Lok NS, Lau CP, Ayes GM. Can transvenous atrial defibrillation be performed without sedation? (abstr) European Journal of Clinical Pacing and Electrophysiology 1996; 6: 55.
23. Chu PL, Ngai-Sang L. A comparison of transvenous atrial defibrillation of acute and chronic atrial fibrillation and the effect of intravenous sotalol on human atrial defibrillation threshold. Pacing Clin Electrophysiol 1997; 20 (Part I): 2442-52.
24. Cooper RAS, Plumb VJ, Epstein AE, Kay GN, Ideker EI. Marked reduction in internal atrial defibrillation threshold with dual-current pathways and sequential shocks in humans. Circulation 1998; 97: 2527-35.
25. Prakash A, Saksena S, Mathew Ph, Krol RB. Internal atrial defibrillation: effect on sinus and atrioventricular nodal function and implanted cardiac pacemakers. Pacing Clin Electrophysiol 1997; 20: 2434-41.
26. Waktare J, Camm J. Acute treatment of atrial fibrillation: why and when to maintain sinus rhythm. Am J Cardiol 1998; 81 (5A): 3C-15C.