A comparison of treatment of atrial fibrillation with low-energy intracardiac cardioversion and conventional external cardioversion


I. Medizinische Klinik, Klinikum rechts der Isar der Technischen Universität München, and Deutsches Herzzentrum München, Klinik an der Technischen Universität München, Munich, Germany

Aim Low-energy (1 to 15 J), catheter-based intracardiac cardioversion was compared with transthoracic external cardioversion (360 J) in a prospective, cross-over clinical trial.

Methods and results In 187 consecutive patients with chronic atrial fibrillation, over a period of a mean of 10.0 ± 7.3 (SD) months, 217 cardioversion attempts were made. Intracardiac shocks were randomly applied between two 6-F catheters located in either the right atrium and coronary sinus or between the right atrium and left pulmonary artery. When a cardioversion attempt with one method failed, the other method was implemented. After cardioversion, all patients were treated orally with sotalol with a mean daily dose of 174 ± 54 mg.

Internal cardioversion was more effective than external cardioversion (65/70=93% vs 92/117=79%, P<0.01). The mean energy for successful cardioversion was 5.8 ± 3.2 J for the internal and 313 ± 71 J for the external cardioversion group. At a mean follow-up of 12.5 ± 6.4 months, 48% (38%) of the patients treated with internal (external) cardioversion were in sinus rhythm (P<0.05).

In 22 of 25 patients in whom external cardioversion failed, sinus rhythm was restored with internal cardioversion at a mean energy of 6.5 ± 3.0 J. Overweight patients had twice the risk of unsuccessful external cardioversion.

Conclusions Internal cardioversion is effective in restoring sinus rhythm. It might be indicated in patients in whom external cardioversion had failed or in whom external cardioversion is assumed to be difficult or even contraindicated.

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Key Words: Atrial fibrillation, defibrillation, internal cardioversion, sinus rhythm.

Introduction

Atrial fibrillation is a common arrhythmia; its incidence is estimated to be 4–6% of the U.S. population above the age of 60 years. Its prevalence increases to 10% for persons aged 75 years or older. In the past, many clinicians considered atrial fibrillation to be a benign arrhythmia; its morbidity and frequently incapacitating symptoms were often underestimated.

Established methods for converting atrial fibrillation to sinus rhythm include treatment with antiarrhythmic drugs and application of external high energy shocks. Success rates of 40 to 70% have been reported with antiarrhythmic drugs. The reported success rates for external cardioversion range from 61% to 90%. In patients in whom external cardioversion had failed and in whom atrial fibrillation was not well tolerated despite medication, advanced catheter techniques aimed at restoring sinus rhythm have been evaluated. Internal cardioversion of atrial fibrillation via these techniques used high energies, ranging from 100 to 360 J, and either totally right-sided intracardiac electrode systems or right atrial catheter-to-chest wall electrode systems.

Recent advances using a coronary sinus and a right atrial catheter-based electrode system for cardioversion of acute atrial fibrillation has proven effective in animals. Following promising results in a feasibility study which revealed internal cardioversion to be effective and safe, we started a trial in a larger series of patients with chronic atrial fibrillation and compared this new technique of internal cardioversion to conventional external cardioversion.
Table 1 Characteristics (mean ± SD) of patients with chronic atrial fibrillation undergoing elective cardioversion

<table>
<thead>
<tr>
<th></th>
<th>Primary treatment — external cardioversion (total)</th>
<th>Primary treatment — internal cardioversion (total)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>117</td>
<td>70</td>
</tr>
<tr>
<td>Age (years)</td>
<td>60 ± 10</td>
<td>59 ± 11</td>
</tr>
<tr>
<td>Male/female ratio</td>
<td>80/37</td>
<td>53/17</td>
</tr>
<tr>
<td>Body weight (kg)</td>
<td>78 ± 13</td>
<td>81 ± 16</td>
</tr>
<tr>
<td>Left atrial size (mm)</td>
<td>60 ± 7</td>
<td>59 ± 6</td>
</tr>
<tr>
<td>Underlying heart disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>35 (30%)</td>
<td>19 (27%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>19 (10%)</td>
<td>15 (21%)</td>
</tr>
<tr>
<td>Valvular heart disease</td>
<td>23 (20%)</td>
<td>14 (20%)</td>
</tr>
<tr>
<td>Dilated cardiomyopathy</td>
<td>14 (12%)</td>
<td>8 (12%)</td>
</tr>
<tr>
<td>Hypertrophic cardiomyopathy</td>
<td>2 (2%)</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Lone atrial fibrillation</td>
<td>20 (17%)</td>
<td>10 (14%)</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>4 (3%)</td>
<td>3 (4%)</td>
</tr>
<tr>
<td>Duration of current episode of AF (months)</td>
<td>9-8 ± 7-8</td>
<td>10-6 ± 8-5</td>
</tr>
<tr>
<td>Prior unsuccessful attempts of pharmacological conversion (n)</td>
<td>61 (52%)</td>
<td>37 (53%)</td>
</tr>
</tbody>
</table>

AF = atrial fibrillation.

Table 2 Acute and long-term outcome of external and internal cardioversion in patients with chronic atrial fibrillation. Values are mean ± SD

<table>
<thead>
<tr>
<th>Patients</th>
<th>DFT (J)</th>
<th>Impedance (Ω)</th>
<th>Acute outcome</th>
<th>Duration of follow-up (months)</th>
<th>Intention-to-treat long-term outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>External cardioversion attempts (n=117)</td>
<td>313 ± 71</td>
<td>nm</td>
<td>92 success (78%)</td>
<td>13-0 ± 6-4</td>
<td>SR 47/117</td>
</tr>
<tr>
<td>Internal cardioversion attempts (n=70)</td>
<td>5-8 ± 3-2</td>
<td>56-3 ± 8-6</td>
<td>65 success (93%)</td>
<td>12-5 ± 6-4</td>
<td>SR 35/70</td>
</tr>
<tr>
<td>Internal cardioversion after failed external cardioversion attempts (n=25)</td>
<td>7-2 ± 3-1</td>
<td>55-1 ± 8-3</td>
<td>22 success (88%)</td>
<td>12-4 ± 6-0</td>
<td>SR 11/25</td>
</tr>
<tr>
<td>External cardioversion after failed internal cardioversion attempts (n=5)</td>
<td>360</td>
<td>nm</td>
<td>1 success (20%)</td>
<td>11-9 ± 5-2</td>
<td>SR 0/5</td>
</tr>
</tbody>
</table>

AF = atrial fibrillation; DFT = defibrillation threshold; nm = not measured; SR = sinus rhythm.

Methods

Patient characteristics

We studied 187 consecutive patients with chronic atrial fibrillation of at least two weeks duration (mean ± SD, 10-0 ± 7-3 months, range 0-25-37 months). Patient characteristics are shown in Table 1. After a thorough explanation of both treatment forms, patients were given a chance to select their preferred form of treatment. External conversion was performed in 117 patients (external cardioversion group) and internal cardioversion in 70 (internal cardioversion group). Additionally, internal cardioversion was performed in 25 patients whose primary external cardioversion attempt had failed (crossover group); external cardioversion was performed in five patients whose primary internal cardioversion had failed. In this crossover group, patients underwent the alternative cardioversion method without a chance of option (Table 2). Altogether, a total of 95 patients underwent internal cardioversion and 122 external cardioversion; a total of 217 external and internal cardioversion attempts were included in this study.

Informed consent and documentation

Benefits and risks of the study were discussed with the patients. An informed consent form was obtained from all patients. The study was performed according to the protocol approved by the Human Research Ethics Committee of the Klinikum rechts der Isar on 27 April 1993.

Study protocol

Patients aged 21 to 75 years were enrolled if the following selection criteria were fulfilled: chronic atrial fibrillation.
fibrillation of at least 14 days' duration, documented by serial electrocardiogram; effective anticoagulation with warfarin for at least 2 weeks (INR 2-7-4-2); absence of left atrial or atrial appendage thrombus (as assessed by transoesophageal echocardiography immediately prior to cardioversion. This was mandatory in all patients with anticoagulation <2 weeks, unless technically impracticable).

Patients were excluded from the study when there was evidence of digitalis toxicity, abnormal electrolyte levels or hyperthyroidism. Furthermore, patients with a history of long QT syndrome or acute myocardial infarction within the past 6 weeks were excluded from the study, as were patients with a history of embolism. Clinical examination was performed and medical history taken. Routine 12-lead ECG, 24-h Holter monitoring, chest X-ray, routine laboratory and thyroid parameters, M-mode and Doppler echocardiography were assessed in all patients.

Definitions

Atrial fibrillation was defined from the electrocardiogram as a narrow QRS complex rhythm without P waves or flutter waves and with an irregular ventricular response. Successful cardioversion was defined as the resumption of sinus rhythm within 30 s of the shock and persisting for at least 1 min.

Anticoagulation

Patients with atrial fibrillation were treated with warfarin for at least 3 weeks prior to defibrillation. The dose was adjusted to maintain an international normalized ratio (INR) of 2-7-4-2. Warfarin was withheld 48 h prior to cardioversion, and an INR repeated on that day was required to be <3-0 in order to perform the procedure, in view of the risk of bleeding from puncture sites. Warfarin was resumed following cardioversion and continued for 4 weeks in those patients successfully reverted to sinus rhythm, and indefinitely in patients who remained in atrial fibrillation. The long-term INR was adjusted individually on patient characteristics.

Protocol for external cardioversion

External cardioversion was performed according to the best known established methods. Under the supervision of an anaesthetist, patients were administered a short-acting narcotic (methohexital). One to a maximum of three R wave-triggered shocks of increasing energy starting with one 200 J shock, a second of 300 J and, if necessary, a third of 360 J (Lohmeier D501, Lohmeier, Inc., Munich, Germany) were applied. We used two paddles, one placed on the anterior chest wall of the patient, the other in an axillary position. Between unsuccessful defibrillation attempts, at least 1 min was permitted to elapse before the next shock was applied. Criteria for discontinuation were patient discomfort, complications such as induction of proarrhythmia or skin burns, and the limitation to three shocks. We obtained creatine kinase data before, immediately after, and 6 h after each shock protocol. If the final shock of 360 J had failed, internal cardioversion was attempted in a subsequent session.

Protocol for internal conversion

We used temporary, custom-built 6-F catheters (Elecath, Rahway, NJ, U.S.A.) with an active surface of 2-5 cm² consisting of nine parallel stainless steel rings which were inserted through the right femoral vein. One catheter was positioned in the lower right atrium so that the majority of the catheter electrodes had firm contact with the right atrial free wall. The second defibrillation electrode was placed at random either in the coronary sinus or in the left pulmonary artery (Fig. 1). In addition, a standard diagnostic 6-F quadripolar catheter was positioned in the right atrium for recording and stimulation. Internal cardioversion was performed in the cardiac catheterization laboratory. The patients were initially sedated with 5 mg diazepam orally. Immediately before cardioversion, 2-0 to 12 mg midazolam were administered intravenously. Creatine kinase values were obtained before and immediately after each cardioversion attempt.

Defibrillation threshold was defined as the lowest shock intensity that converted atrial fibrillation to sinus rhythm. The right electrode served as cathode. Biphasic shocks of 3 ms/2 ms with phases separated by 0-2 ms were used. The shocks were delivered by an external defibrillator (Ventritex HVS-02, Ventritex, Sunnyvale, CA, U.S.A.) and synchronized to the R-wave. Prior to the application of the shocks, a custom-built ECG amplifier and filter with variable gain was adjusted to assure correct synchronization, which was confirmed visually on an oscilloscope (Gould 6000 S, Gould, Ilford, U.K.). Starting with a test shock of 60 V intensity, the energy was increased in 40 V steps until cardioversion was achieved. Criteria for quitting were patient discomfort, complications, such as proarrhythmia or major bleeding and shock energies above 15 J. Between unsuccessful defibrillation attempts, at least 1 min was permitted to elapse before the next shock was applied. During the study, a 12-lead ECG and the intra-atrial signals were recorded and stored by an EP Lab, version 6-0 (Quinton Electrophysiology, Inc., Ontario, Canada) (Fig. 2).

The delivered voltage, current and shock morphology for each shock were recorded using a Macintosh computer. Impedance and energy were

Eur Heart J, Vol. 18, November 1997
Intracardiac low-energy conversion

Figure 1 (Top): one defibrillation catheter with nine stainless steel electrode rings is placed in the mid-right atrium via a right femoral vein access. The second defibrillation catheter is introduced via the internal jugular vein and advanced to a distal coronary sinus position. (Bottom): in this patient, the right atrial defibrillation catheter is applied via a femoral vein approach. The second defibrillation catheter is placed in the left pulmonary artery. The pictures were taken in a posterior-anterior projection.

calculated by means of a customized LabVIEW software program (National Instruments, Austin, TX, U.S.A.).

Follow-up evaluation

All patients were followed in our outpatient department. A 12-lead ECG was obtained 1 week, 1 month and 3-12 months follow-up or earlier if the patient experienced symptoms suggestive of recurrent atrial fibrillation. At the time of cardioversion, antiarrhythmic medication had been withdrawn at least two half-lives beforehand. After effective conversion to sinus rhythm, a treatment with oral sotalol of at least 80 mg b.i.d. (mean daily dose ± SD, 174 ± 54 mg, range 160 to 400 mg) was started in all patients. Additionally, ACE inhibitors, diuretics and digitalis were administered, based on the clinical status of the patient. In patients with persistent sinus rhythm, anticoagulation was discontinued 4 weeks after successful conversion.

Statistical analysis

Continuous variables are expressed as mean ± standard deviation (SD). Statistical analyses were performed using ‘Statistical Package for Social Sciences’ for uni- and multivariate analyses with respect to influence of clinical variables, outcome, shock parameters and follow-up (SPSS, Inc., Chicago, IL, U.S.A.). The recurrence data were analysed using SPSS life-table survival analysis. A P-value of <0.05 was considered to indicate statistical significance.

Results

Patient clinical characteristics and general results

There were no significant differences between the two cardioversion method groups regarding their clinical characteristics (Table 1). Of note, our patients had an enlarged left atrium of 59.1 ± 6.3 mm and a relatively long mean duration of atrial fibrillation, of 10.0 ± 7.3 months (range 0.5 to 37 months). In 48 of the 187 patients, atrial fibrillation had been present for more than 12 months.

In 61 of the 177 patients in the external group and in 37 of the 70 patients in the internal group, prior unsuccessful attempts at pharmacological conversion had been made (ns, Table 1).

Complications

One female patient in the internal cardioversion group suffered immediate ventricular fibrillation due to poor synchronization, which could be stopped by external shock application. Since neither method succeeded in restoration of sinus rhythm in her further course, her atrial arrhythmia was considered intractable, and no additional cardioversion attempts were undertaken.

With energy delivery synchronized to the ventricular electrogram, no further ventricular fibrillation episodes occurred in either group. There were no acute proarrhythmic effects or thromboembolic complications in either group, following delivery of the synchronized shocks. In the internal group, a major femoral haematoma resulted after the procedure in one patient. In the external group, skin burns and/or myalgia postcardioversion were encountered in 46 patients. We observed no relevant increase in creatine kinase levels in the internal group, but a slight increase in 81 patients of the external group (mean of 55 U·1⁻¹ before and 84 U·1⁻¹ 6 h after the protocol, P<0.05).

Acute efficacy of cardioversion

Table 2 presents the results from the external and internal cardioversion groups. The mean energy for
successful cardioversion was 313 ± 71 J for the external and 5.8 ± 3.2 J for the internal cardioversion group. The internal shocks had significantly higher efficacy compared with the external shocks (65/70 = 93% vs 92/117 = 79%, P<0.01).

Overweight patients (body mass index > 25 kg m⁻²) undergoing external cardioversion had twice the risk (odds ratio = 2.3; 95% CI 1.4 to 4.3) (P<0.01) of unsuccessful external cardioversion compared with a body mass index < 25 kg m⁻².

Table 2 also shows results from patients initially treated with external cardioversion which failed to restore sinus rhythm and who were then treated with internal cardioversion (cross-over group). In 22 of these 25 patients, sinus rhythm was restored at a mean energy of 6.5 ± 3.0 J with internal cardioversion. In two of the three patients that failed, sinus rhythm was initially restored by internal cardioversion, but this was sustained for less than 1 min, despite repeated short-term successful internal cardioversions. This cross-over group...

Eur Heart J. Vol. 18, November 1997
Intracardiac low-energy conversion

Figure 3 (Top): relationship between energy requirements and duration of atrial fibrillation in months for successful internal cardioversion of atrial fibrillation ($P<0.05$). (Bottom): relationship between energy requirements and left atrial diameters in mm for successful internal cardioversion of atrial fibrillation ($P<0.05$).

had higher energy requirements compared with the patients of the primary internal cardioversion group ($6.5 \pm 3.0$ J vs $5.8 \pm 3.2$ J, $P=0.05$). In the five patients not converted by primary internal cardioversion, external cardioversion was successful in one patient.

Comparing the efficacy of the two treatment methods for all patients ($n=95$) treated with either internal (cardioversion group, $n=70$, and crossover group, $n=25$) or external intervention, the success rate of internal ($87/95=92\%$) cardioversion was significantly higher than that of external cardioversion ($93/122=76\%$ patients, $P=0.01$).

Correlation of energy requirements with potential clinical predictors

There was no correlation between energy requirement for successful external cardioversion and either duration of atrial fibrillation or left atrial diameter (ns). This is an expected finding when considering that the energy steps in this group were few in number and large in size.

In the patients treated with internal cardioversion, there was a significant correlation of energy requirements and duration of atrial fibrillation ($P<0.05$). Moreover, there was a significant correlation between energy requirements and left atrial size ($P<0.05$) (Fig. 3).

Long-term clinical outcome

On an intention-to-treat basis, 47 of the 122 patients treated with external cardioversion (38\%) were in sinus rhythm after a mean follow-up of $12.5 \pm 6.4$ months (range 2 to 33 months), as were 46 of the 95 patients treated with internal cardioversion (48\%). This demonstrates a significantly higher chance for a patient being in sinus rhythm after 1 year when treated with internal cardioversion ($P<0.05$) as compared to external cardioversion. Figure 4 depicts the life table analysis showing the cumulative proportion of patients remaining in sinus rhythm on an intention-to-treat basis.

Analysis of the maintenance of sinus rhythm in patients who had been successfully converted by either treatment method showed that this difference is primarily due to the different initial conversion rates, since at the mean follow-up of $12.5 \pm 6.4$ months, 46 of the 87 patients (53\%) converted successfully with internal cardioversion remained in sinus rhythm, while 47 of the 93 patients (51\%) converted successfully with external cardioversion were in sinus rhythm. Atrial fibrillation recurred after a mean of $2.1 \pm 1.4$ months in the internal group and after $2.2 \pm 1.0$ months in external group (ns).

When comparing the long-term outcome between these two groups with patients ($n=25$) treated by internal cardioversion after failed external cardioversion attempts (Table 2), there was no difference regarding the maintenance of sinus rhythm at one year follow-up.

Eur Heart J, Vol. 18, November 1997
Patients in whom atrial fibrillation had persisted for more than 2 months had a higher risk of relapsing into atrial fibrillation than patients with atrial fibrillation that had lasted less than 2 months (odds ratio = 2.6; 95% CI 1.2 to 5.8) (P<0.01).

**Discussion**

**Feasibility**

This study shows that internal cardioversion of patients with chronic atrial fibrillation can be achieved with energies lower than those used for conventional external cardioversion. In this study, the efficacy rate of 93% for primary internal cardioversion was significantly higher than the 79% rate for external cardioversion (P<0.01). The success rate for external cardioversion in our patients is in line with literature reports.

The exact mechanisms for the success of internal cardioversion can only be anticipated. The creation of a homogenous electrical field with sufficient strength is mandatory for conversion of ventricular fibrillation. The same may hold true for atrial fibrillation. With respect to homogeneity of field strength, one would assume that the direct application of the energy to the two areas within or surrounding the heart should result in increased myocardial field strength and decreased energy loss. This may also explain in part why previous attempts of high and low energy shocks delivered between one electrode in the heart and one skin electrode, or between electrodes not incorporating the left side of the heart, had less favourable results compared with the new method of internal cardioversion described in this paper. This holds true for lead configuration such as RA-axillary patch or RV-SVC electrode configurations. Underscoring the importance of field strength may be the fact that patients in whom external cardioversion failed had a significantly higher body weight (P<0.05) compared with patients in whom external cardioversion was successful.

In contrast to the energies required for conversion of induced atrial fibrillation in animals and in man, which range from 0.5 to 2.5 J on average, we found higher energy levels with a mean of 5.8 ± 3.2 J in our patients with chronic atrial fibrillation. This may be explained in part by the longer duration of atrial fibrillation in our patients, and by the use of the pulmonary artery electrode location, all of which could have resulted in a higher actual or perceived energy requirement.

Energy for internal cardioversion is lower than the energy normally applied with conventional direct-current cardioversion. Therefore, deep sedation was not required; all patients undergoing internal cardioversion were in a conscious or moderately sedated state during shock application following administration of diazepam and midazolam. Dependent on the individual level of sedation, patients described moderate discomfort during shock application detailed as a tolerable hit on the thorax. In the follow-up, none of the patients remembered the cardioversion as an intolerable event. There was no anaesthetist present during internal cardioversion.

**Safety of cardioversion**

With any kind of energy application to the heart at or exceeding the pacing threshold, a certain risk of arrhythmia induction is present, even with synchronized shocks. Animal studies suggest that with short preceding ventricular cycle lengths of less than 300 ms, even with synchronized shocks a certain risk of ventricular arrhythmia induction is present, but at longer intervals this risk becomes negligible. To avoid improper shock application, internal cardioversion should not be attempted while R-R intervals are below 300 ms. We have installed a device in our shock application system that prevents triggering within 500 ms of the previous QRS complex.

Positioning of defibrillation electrodes in the right atrium, pulmonary artery or coronary sinus raises the question of whether damage can result from the energy delivered via the defibrillation electrodes.

Chronically implanted defibrillation electrodes in the coronary sinus and other locations in the heart have been used for shock application of energies up to 30 J for treatment of ventricular fibrillation in patients without adverse effects. Therefore, we assumed that atrial defibrillation from these sites would result in no myocardial damage but, since we lack human histological findings, we have no definite proof for this assumption. Our data did not reveal an increase in the levels of creatinine kinase.

**Follow-up**

After conversion, treatment with oral sotalol was started in all patients, based on the effect on maintenance rate of sinus rhythm after direct-current conversion of atrial fibrillation with this drug. Our follow-up data of more than 50% of patients in sinus rhythm after primary successful cardioversion confirm these findings. Despite our initial recommendation for treatment with oral sotalol, patient compliance with long-term therapy with this drug was not studied or considered for the calculation of maintenance of sinus rhythm. Indeed, there was no significant difference regarding preservation of sinus rhythm following successful external or internal cardioversion. There was also no difference with regard to the acute outcome and the maintenance rate of sinus rhythm in the 25 patients in whom external cardioversion attempts had failed and internal cardioversion was successful. This indicates that an internal low-energy cardioversion attempt may be worthwhile even in patients in whom prior external cardioversion attempts had failed.
Clinical implications and outlook

External cardioversion is non-invasive, can be easily applied, and is the standard non-pharmaceutical method for cardioversion of atrial fibrillation.

Internal cardioversion uses only a part of the energy applied externally, shows a higher success rate, but necessitates the invasive insertion of two catheters requiring fluoroscopy. It requires less sedation than external cardioversion and allows stimulation with post-conversion slow heart rates, both as a treatment for bradycardic episodes and for temporary overdrive suppression, especially in conjunction with the use of intravenous antiarrhythmic medication. Internal cardioversion is highly effective in returning patients to sinus rhythm. Based upon our current knowledge and experience with this new method, it might be indicated in patients in whom external cardioversion had failed or external cardioversion is assumed to be difficult or even contraindicated. Using the technique of internal cardioversion, an implantable atrial defibrillator which treats recurrent episodes of atrial fibrillation[23,28] is currently undergoing clinical investigation as well.

Limitations

This was a prospective but not randomized study, although cross-over of patients did occur from the external cardioversion group to the internal cardioversion group and vice-versa. The mode of treatment, external or internal cardioversion, was not randomized since, at the time the study was begun, it was considered unethical to randomize patients to a form of treatment with this new method, it might be indicated in patients in whom external cardioversion had failed or external cardioversion is assumed to be difficult or even contraindicated. Using the technique of internal cardioversion, an implantable atrial defibrillator which treats recurrent episodes of atrial fibrillation[23,28] is currently undergoing clinical investigation as well.

References


