

Analysis of Current Management of Atrial Fibrillation in the Acute Setting: GEFAUR-1 Study

Carmen del Arco, MD

From the Arrhythmia Division, Spanish Society of Emergency Medicine, Madrid, Spain.

Alfonso Martín, MD

Pedro Laguna, MD

Pedro Gargantilla, MD,

on behalf of the investigators

in the Spanish Atrial

Fibrillation in Emergency

Medicine Study Group

(GEFAUR)*

Study objective: Limited information relative to the management of atrial fibrillation in the emergency department (ED) daily practice is available. This study evaluates current management of atrial fibrillation in this setting to identify areas for practice improvement.

Methods: This was a prospective multicenter observational study carried out in 12 EDs. Adults in whom atrial fibrillation was demonstrated in an ECG obtained in the ED were included. Clinical variables and atrial fibrillation management in the ED were prospectively collected by the treating physicians using a standardized questionnaire. Patients with rapid ventricular response (>100 beats/min) were considered eligible for rate control, and patients with recent-onset episodes (<48 hours) were eligible for rhythm control.

Results: Of 1,178 patients, 41% presented with a rapid ventricular response and 21% had recent-onset episodes. Rhythm control was attempted in 42% of eligible patients, with antiarrhythmic drugs in 88% of cases (I-C drugs in 44% of patients; amiodarone in 43% of patients). Overall effectiveness of pharmacologic cardioversion was 63% (amiodarone 54.5%, flecainide 93%), whereas electrocardioversion was effective in 87.5% of cases. Rate control was performed in 68.3% of eligible patients (overall effectiveness 47.8%); digoxin was used in 67% of cases (effectiveness 45%). Both strategies were selected in 4.5% of cases, whereas no treatment for atrial fibrillation was performed in 60% of patients.

Conclusion: In our ED population, rate-control effectiveness is poor and rhythm control is not attempted in most recent-onset episodes. Methods to improve rate-control effectiveness, the selection of patients for rhythm control, and the use of electrocardioversion appear warranted. [Ann Emerg Med. 2005;46:424-430.]

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INTRODUCTION

Background

Atrial fibrillation constitutes a growing health care problem because of its increasing prevalence, substantial complications, and associated costs.¹ Although general agreement exists in

literature about the role of stroke prophylaxis in these patients, the optimal strategy for the management of the arrhythmia remains uncertain²⁻⁴: cardioversion and treatment with antiarrhythmic drugs to maintain sinus rhythm (rhythm control) or just control of the ventricular rate, allowing atrial fibrillation to persist. A number of clinical trials have been conducted to determine the optimal medical management of atrial fibrillation,⁵⁻⁷ but these were not acute studies; they studied patients

*The participating investigators are listed in the [Appendix](#).

Editor's Capsule Summary

What is already known on this topic

For patients with atrial fibrillation, the performance of rate and rhythm control remains the mainstay for therapy in the emergency department (ED).

What question this study addressed

This secondary analysis of a multicenter trial of atrial fibrillation care (Spanish Atrial Fibrillation in Emergency Medicine Study Group-1) describes how often rate and rhythm control were attempted in the ED, the methods used, and the success of those methods.

What this study adds to our knowledge

Rhythm control was attempted in 42% of subjects with less than 48 hours of atrial fibrillation and was successful in 65% of subjects. Rate control through pharmacologic therapy was used in 68% of subjects whose pulse rate exceeded 100 beats/min and was effective in 48% of cases.

How this might change clinical practice

These data provide a basis for improving clinical pathways for the management of atrial fibrillation.

with minimally symptomatic long-term atrial fibrillation. Additionally, some reluctance exists to follow their conclusions in routine practice that patients' clinical characteristics and conditions of work greatly vary from those of randomized clinical trials.⁸

Importance

Emergency departments (EDs) account for a large and increasing number of visits (>102 million in United States in 1999),⁹ mainly of aged persons and patients with cardiovascular diseases, important at-risk populations for atrial fibrillation.¹⁰ Additionally, atrial fibrillation is the most frequently managed arrhythmia in the ED, with a prevalence of 1.1% to 3.6% of the general medical ED visits.^{11,12} ED practice differs greatly from the "ideal" conditions of clinical trials and constitutes an accurate reflection of routine practice in patients' clinical profile and management.^{12,13} Thus, the study of the patterns of management of atrial fibrillation in this setting could help to identify areas for quality assessment and management improvement in the ED routine practice.¹⁴

Goals of This Investigation

The objectives of this current analysis of the Spanish Atrial Fibrillation in Emergency Medicine (GEFAUR-1: Grupo para el Estudio de la Fibrilación Auricular en Urgencias) study were to determine the current management (rhythm or rate control) of atrial fibrillation, its effectiveness, and the factors related to the election of each strategy,

identifying areas for management improvement, in a representative sample of the acute-setting daily practice.

MATERIALS AND METHODS

Study Design and Setting

The GEFAUR-1 was a prospective, observational, multicenter study carried out in the ED of 12 hospitals of the National Health System in Madrid, Spain, between June 15 and August 1, 2000, promoted by the Scientific Committee of the Spanish Society of Emergency Medicine. A detailed description of the GEFAUR study methodology has been published elsewhere.¹³ The institutional review board of the Spanish Society of Emergency Medicine approved the study protocol. The protocol was blinded to guarantee patients' and physicians' confidentiality. The peculiarities of emergency medicine in Spain, the demographics of our population, and risk factors for stroke and thromboprophylaxis in our series have been previously described in detail.¹² This article is an analysis of the GEFAUR-1 data set, concerning atrial fibrillation management (rate or rhythm control).

Selection of Participants

All patients older than 14 years and who were treated in the ED medical areas, and in whom atrial fibrillation was demonstrated in an ECG (obtained when the treating physician considered it necessary during clinical evaluation), were eligible for inclusion. Patients from pediatrics, obstetrics, psychiatry, orthopedics, otolaryngology, and ophthalmology were excluded, although if they were transferred to the medical area for consultation, they were available for inclusion. We included all episodes of atrial fibrillation with the aim to state the impact of atrial fibrillation in ED daily work, so reenrollment of patients was not prevented. The diagnosis of atrial fibrillation and their types (paroxysmal and chronic [persistent or permanent]) was made prospectively following criteria from Levy et al.¹⁵ Comorbidity was defined according to the criteria from the Framingham Heart Study.¹⁶

Data Collection and Processing

The emergency physicians performed treatment and thereafter prospectively filled out data forms for each patient, with the following information: demographics, structural heart disease, previous episodes of atrial fibrillation, current antiarrhythmic therapy or stroke prophylaxis, risk factors for stroke,¹⁷ disability, comorbidity, the reason for attending the ED, clinical evaluation, duration of the current episode (<48 hours, >48 hours, or unknown), final patients' disposition, and the treatment for atrial fibrillation prescribed in the ED: rate control (drug used and its effectiveness), rhythm control (electrical or pharmacologic and whether it was effective), or stroke prophylaxis (anticoagulants, antiplatelet therapy, or both). If atrial fibrillation lasted less than 48 hours and rhythm control was not attempted, the attending physician was asked to note the reasons for this decision from a set of multiple-choice possibilities: doubts about the duration of the episode, poor

Table 1. Demographics and clinical characteristics of patients.

Variable No. (%)	Overall (n=1,178)	Rhythm Control (n=119)	Rate Control (n=410)
Age, y, mean (SD)	74.6 (12)	63 (14)	72 (12)
Age >75 y	672 (57)	26 (22)	188 (46)
Female sex	702 (60)	62 (52)	258 (63)
Hypertension	669 (57)	47 (39)	222 (54)
Diabetes	262 (22)	16 (13)	90 (22)
Structural HD	562 (47)	49 (41)	184 (45)
Disability	256 (21.78)	8 (6.5)	72 (17.5)
Previous AF	894 (75)	63 (53)	250 (61)
Current treatment	891 (75)	63 (53)	250 (61)
Antiarrhythmics	798 (67)	50 (42)	206 (50)
Anticoagulants	366 (31)	8 (6.7)	80 (19)
Antiplatelets	259 (22)	25 (21)	63 (15)
Risk factors for stroke*	1,043 (88.5)	72 (61)	344 (84)
Pulse rate, beats/min			
Mean (SD)	102 (32)	134 (27)	127 (27)
>100	486 (41)	103 (87)	333 (81.4)
Hemodynamic instability	38 (3.2)	4 (3)	20 (5)
Heart failure in the ED	273 (23)	10 (8)	123 (30)
Duration of AF			
<48 hours	246 (21)	107 (90)	139 (34)
>48 hours	596 (50)	7 (6)	143 (35)
Unknown	336 (28.5)	5 (4)	123 (30)
Palpitation	256 (21)	76 (63.7)	168 (41)
Chest pain	154 (13)	24 (20.4)	68 (16)
Dyspnea	332 (28)	21 (18.6)	143 (34.9)
Disposition			
Discharge	657 (56)	76 (64)	216 (52.7)
Admission	340 (29)	21 (18)	136 (33.3)
Observation	175 (15)	20 (17)	54 (13.2)
Death in the ED	6 (0.5)	0 (0)	3 (0.7)

AF, Atrial fibrillation; HD, heart disease.
*According to the ACCP-1998 guidelines.²⁰

therapeutic compliance, disability, drug abuse (alcohol or illicit substances), structural heart disease, inadequate level of anticoagulation, lack of knowledge about the procedure, patient's or physician's rejection, or spontaneous conversion. The variables on the data-collection sheet were encoded on the basis of a single table established by the study coordination committee.¹³ This information was collected by a combination of patient self-reporting and reviewing of medical records. Copies of the GEFAUR-1 study protocol (including definitions, comorbidity, and codes) were provided to all the treating physicians. No therapeutic recommendations or specific education about atrial fibrillation and rate or rhythm control were done by the study coordination committee during the data collection.

Diagnoses of structural heart disease were based on the existence of an echocardiogram in the patient's medical records or hospital's database, when available. In the remaining cases, cardiopathy was ruled out by the absence of findings in the physical examination (heart murmurs), ECG evaluation (ST-segment or T-wave abnormalities, bundle-branch block) and

chest radiograph films.¹³ Disability was defined as dependence for the daily life activities according to the Katz scale.¹⁸

Hemodynamic instability was defined as a symptomatic decrease in blood pressure (<90/50 mm Hg or a decrease of 30 mm Hg from previous blood pressure) associated with organ dysfunction (severe heart failure or angor pectoris, respiratory distress, or other life-threatening conditions).^{13,19}

Outcome Measures

The main outcome measures of the GEFAUR-1 study were 3: the performance of rate control, the performance of rhythm control, and the prescription of stroke prophylaxis in patients with atrial fibrillation who attended the EDs during the study period. As previously mentioned, the latter was analyzed in detail elsewhere.¹²

Additionally, we analyzed atrial fibrillation management in the ED. The study coordination committee independently reviewed all the datasheets and then compared the management performed in each case with the guideline recommendations. According to this, we considered that hemodynamically unstable patients should have undergone immediate synchronized electrocardioversion; the rest of patients were eligible for rate control if their pulse rate after 30 minutes at rest was greater than 100 beats/min. Treatment was considered effective if pulse rate 60 to 90 beats/min at rest was achieved.^{1,13} Atrial fibrillation lasting less than 48 hours was considered of recent onset and, therefore, eligible for cardioversion in the ED.^{1,13} The treating physician was free to decide the procedure, electrical or pharmacologic and, in the latter case, the drug to be used. Rhythm control was considered effective if stable sinus rhythm (>2 hours) was achieved. In stable patients with duration of atrial fibrillation greater than 48 hours or unknown, cardioversion should be evaluated and performed electively in other health care settings.

Primary Data Analysis

Statistical analyses were done with SAS for Windows statistical software package (version 8.0, SAS Institute, Inc., Chicago, IL). Because of the characteristics and objectives of our observational study, data (demographics, comorbidity, clinical evaluation, management in the ED, and patient's disposition) are presented using descriptive statistics. Continuous variables are presented as mean±SD, and categorical variables are given as proportions.

We compared, to evaluate the homogeneity of the samples and the management among the hospitals, only the demographics, previous diseases, clinical presentation, evaluation in the ED, and patients' management of the 12 EDs, using the χ^2 test for categorical variables and the Student *t* test for the continuous ones. This showed only small differences (without clinical relevance or implications for therapy) in the number of elderly patients within the health areas.

The responsible investigator of each hospital reviewed the ED medical records daily to avoid protocol violations and to confirm the data collected. In addition, we performed an

external monitoring study to confirm that there were no recruitment losses of clinical importance.¹²

RESULTS

Characteristics of Study Subjects

During the study period, there were 66,146 visits to the ED medical areas, and 1,178 episodes of atrial fibrillation were included (3.6% of the medical ED visits). There were no protocol violations of clinical importance in the recruitment: only 11 eligible patients were missed or the data collection forms were not accurately filled out.

Some degree of disability was present in 21% of patients and reached 28% in the population older than 75 years (36% of which were completely dependent). The treating physicians considered that the rapid ventricular response was a result of noncardiac diseases (mainly fever) in 48 (10%) cases. Additionally, hemodynamic instability was a result of noncardiac conditions in 4 (11%) cases. The characteristics of the patients are listed in Table 1. Risk factors for stroke and thromboprophylaxis in our population have been analyzed in detail elsewhere.¹²

Rate or rhythm control was performed on 470 (39.9%) patients in the ED. Clinical characteristics of all patients for whom rate or rhythm control was attempted in the ED are identified in Table 1.

Symptoms that caused the ED visit were related to atrial fibrillation in 732 (62%) patients (palpitation, dyspnea, or chest pain). Rhythm control was attempted in 103 (14%) of these symptomatic patients, and rate control was attempted in 329 (45%) of them.

There were 246 (20.9%) patients with a duration of atrial fibrillation less than 48 hours and therefore who were eligible for rhythm control; this strategy was attempted in 101 (42%) patients. Antiarrhythmic drugs were selected for rhythm control in 88% of cases, direct-current cardioversion in only 6.1% of cases, and both procedures in 4% of them. Preferred drugs for rhythm control were amiodarone (43%), flecainide (26%), and propafenone (18%). Amiodarone was preferably indicated in patients with structural heart disease (55%), whereas flecainide was used in 72% of cases in patients without evidence of cardiopathy. Electrocardioversion was effective in achieving stable sinus rhythm in 85.7% of cases, whereas the overall effectiveness of the pharmacologic procedure was 63% (amiodarone in 54.5% and flecainide in 93% of cases). Reasons argued by the treating physicians for not attempting sinus-rhythm restoration in 133 (58%) eligible patients were spontaneous conversion (36%), doubts about the real duration of the episode (20%), physician's rejection (13%), severe structural heart disease (3%), disability (3%), inadequate level of anticoagulation (1.3%), patient's rejection (0.6%), and unspecified (22%). Demographic and clinical variables of patients eligible for rhythm control in the ED are listed in Table 2. Additionally, rhythm control was attempted in 18 patients with a duration of the episode greater than 48 hours or unknown.

Table 2. Clinical characteristics of cardioversion-eligible patients (AF <48 hours).

Variable, No. (%)	No Therapy (n=145)	Rhythm Control (n=101)
Age, y, mean (SD)	72 (12)	63 (14)
Age >75 y	111 (77)	22 (22)
Female sex	90 (62)	50 (49.5)
Hypertension	87 (60)	38 (38)
Diabetes	27 (19)	11 (11)
Structural HD	67 (47)	40 (39.6)
Disability	17 (11)	4 (4)
Previous AF	92 (64)	54 (53)
Current treatment	92 (64)	54 (53)
Antiarrhythmics	83 (90)	46 (85)
Anticoagulants	22 (24)	8 (14)
Antiplatelets	30 (32)	22 (40)
Heart failure	21 (15)	7 (7)
Pulse rate, mean (SD), beats/min	115 (30)	134 (27)
Hemodynamic instability	11 (8)	3 (3)
Main complaint		
Palpitation	72 (50)	67 (66)
Chest pain	40 (27)	21 (21)
Dyspnea	39 (27)	18 (18)
Disposition		
Discharge	91(64)	63 (63)
Admission	34 (24)	18 (18)
Observation	16 (11)	18 (18)

There were 486 patients with a pulse rate at rest greater than 100 beats/min and who were therefore eligible for rate control. This strategy was performed in the ED in 332 (68.3%) of patients, with the following regimens: digoxin in 222 (67%) patients, amiodarone in 40 (12%) patients, calcium-channel blockers in 26 (6.5%) patients, and β -blockers in 13 (4%) patients. Control of the ventricular response was achieved in 47.8% of cases, with relevant differences on effectiveness among drugs: β -blockers were effective in 61% of cases, calcium-channel blockers in 48% of cases, digoxin in 45% of cases, and amiodarone in 31% of cases. Clinical and epidemiologic characteristics of patients eligible for rate control in the ED are presented in Table 3. Additionally, rate control was performed in 22 patients with a pulse rate less than or equal to 100 beats/min.

Both treatments (rate and rhythm control) were selected by the treating physicians in 59 (5%) patients. Rate control was performed in these patients with the following regimens: digoxin (32%), amiodarone (20%), propafenone (13%), calcium-channel blockers (12%), β -blockers (3%), and combinations (20%). Rhythm control was attempted using amiodarone (29%), flecainide (26%), propafenone (22%), and electrocardioversion (6%). Conversely, in 708 (60.1%) patients no management strategy for atrial fibrillation was performed in the ED.

LIMITATIONS

Limitations in the GEFAUR-1 study should be acknowledged. The limited number of reasons for avoiding rhythm control noted in the data-collection sheet may have prevented us

Table 3. Characteristics of patients eligible for rate control in the ED (pulse rate >100 beats/min).

Variable, No. (%)	No Therapy (n=154)	Rate Control (n=332)
Age, y, mean (SD)	73 (12)	71 (13)
Age >75 y	77 (50)	143 (43)
Sex, female	83 (53)	211 (63)
Hypertension	75 (48)	177 (53)
Diabetes	24 (15)	72 (22)
Structural HD	81 (52.5)	145 (43)
Disability	31 (20)	51 (16)
Previous AF	109 (71)	193 (58)
Current treatment	98 (64)	187 (57)
Anticoagulants	38 (25)	60 (18)
Heart failure in the ED	22 (14)	93 (28)
Pulse rate, mean (SD), beats/min	128 (16)	137 (19)
Hemodynamic instability	7 (4.5)	19 (6)
Main complaint palpitation	42 (27)	151 (45)
Duration <48 hours	54 (35)	122 (37)
Duration >48 hours	72 (47)	102 (31)
Duration unknown	28 (18)	108 (32)
Disposition		
Discharge	63 (41)	169 (51)
Observation	27 (17)	45 (13)
Admission	48 (31)	110 (33)

from capturing all the situations that might contraindicate therapy. Moreover, we hypothesized that rate control was widely performed, so we did not specifically ask the treating physicians the causes for not attempting this strategy. Because of the main role of this strategy in the current overall atrial fibrillation management, future studies designed to address this question are warranted. Additionally, the use of any guide as a standard for evaluation could be controversial. The suitability of management was determined by the study coordination committee according to the recommendations more widely stated in the literature^{2,4,19-23} and subsequently included in the clinical practice guidelines on management of atrial fibrillation.^{1,24} Therefore, the number of patients in whom rate or rhythm control was correctly avoided would be different if the treating physicians were following other recommendations for atrial fibrillation management. Because of all these factors, determining the appropriateness of care was difficult.

In other words, our data show only short-term results, so effectiveness and outcome beyond the acute phase should not be inferred. Finally, the conduct of a study and the completion of a data form could have an impact on the treating physicians. They could be more concerned about this topic, and the number of patients in whom rate or rhythm control was attempted may be higher than normal.

DISCUSSION

As in other health care settings, it is important to know physicians' daily practice patterns to facilitate the translation of clinical trial data and guideline recommendations into effective clinical care.²⁵ Previous studies on the management of atrial

fibrillation focused on inpatient or office-based populations. The GEFAUR-1 study is based on decisions in an acute setting, with an emphasis on acute management, and reveals that EDs account for a large number of visits by atrial fibrillation patients, principally because of acute symptomatology or complications related to the arrhythmia.

In our series, no management strategy is performed for most patients, which could be acceptable in patients who presented with symptoms unrelated to atrial fibrillation, with long-lasting episodes and controlled ventricular response. Additionally, some patients with rapid pulse rate would have other comorbidities (ie, shock) for which the ventricular rate is appropriate or that can cause tachycardia (fever, hypoxia); for these patients, symptomatic or etiologic treatment could be enough. However, although rate control is performed for a major proportion of eligible patients, its effectiveness is unsatisfactory. This ineffectiveness could be due to the regimens selected, but a certain lack of knowledge about the optimal pulse rate and the consequences of a sustained rapid ventricular response in these patients could also play a role.^{1,24} Digoxin is the preferred drug for rate control in our series, which could be explained, at least in part, by the substantial proportion of patients with heart failure at ED presentation. This drug has poor effectiveness and a slow onset of action²⁰ and could explain the low overall effectiveness of the rate-control strategy in our study. It is fitting to emphasize that β -blockers and calcium-channel blockers are used in a minority of patients, although they are strongly recommended for their rapid onset of action and effectiveness and their influence on prognosis in patients with structural heart disease and comorbidity,^{1,20,24} widely represented in our routine practice population. Considering patients' clinical profile and the poor effectiveness of current strategies, efforts to spread the use of calcium and β -blockers in the acute setting daily practice appear warranted.

Recent-onset episodes of atrial fibrillation are usually considered eligible for rhythm control, with the aim to prevent self-begetting of the arrhythmia and also because effectiveness is higher and anticoagulation can safely be avoided if atrial fibrillation lasts less than 48 hours.^{1,4,5,17,21,22,24} The decision of restoring sinus rhythm in the ED could be controversial, but literature on improving medical treatment supports a multidisciplinary approach to decrease morbidity and mortality from cardiovascular disease and stroke.¹¹ Additionally, patients are likely to visit the ED when symptoms begin,^{10,12,13} and, as previously stated, the sooner rhythm control is attempted, the higher the possibility of success. Rhythm control of recent-onset episodes of atrial fibrillation in the ED appears desirable, with the aim of improving the results of this management strategy, avoiding the risks of anticoagulation. Despite this, rhythm control is attempted in less than half of these patients in our series. Although this could be acceptable in patients with severe heart disease (and, therefore, few possibilities to maintain sinus rhythm after cardioversion) or spontaneous conversion, in 20% of cases the reasons argued were physician's rejection or inadequate level of anticoagulation, which could reflect a certain

lack of knowledge about the indications of thromboprophylaxis in elective cardioversion¹⁷ but also the distrust of the validity of symptoms on achieving the duration of the episode of atrial fibrillation. When the procedures for rhythm control are analyzed, the low use of direct-current (DC) cardioversion in our series is striking, despite its superior effectiveness and the absence of complications noted. This low use could be due to a certain ignorance about the technique or because the ED physicians could consider it a practice to be performed only by other health care professionals, despite the available evidence concerning the feasibility and safety of its performance by their own ED personnel.^{19,21,22} As recommended in the literature,^{1,24} class I-C drugs were used in patients without structural heart disease and who showed associated high effectiveness; conversely, amiodarone was preferably indicated in patients with cardiopathy who showed lower effectiveness, comparable with that described by other authors.²³ It was surprising that only half of patients with hemodynamic instability underwent immediate electrocardioversion. Although in a number of cases atrial fibrillation was a result of noncardiac diseases (and probably hemodynamic instability) and the supportive and etiologic treatments would be more appropriate, this finding has led us to conduct a prospective study to elucidate the reasons for this behavior and to define the subsets of patients who would benefit from other management strategies. Finally, as previously stated in other settings,²⁶ sex was an independent decision factor for treatment, and rhythm control was less frequently performed in women; no explanation for this behavior has been found in the secondary analyses of our series.

In our study, patients' clinical profile differs from those of clinical trials: they were older, with a higher prevalence of comorbidity and current heart failure, important decision factors for management.^{1,4-7} Additionally, almost half of the patients presented with a rapid ventricular response. Taking all these factors into account, and considering the frequency of spontaneous conversion and the high risk of stroke of our population, an initial approach of rate control and stroke prophylaxis should be preferred in hemodynamically stable patients, as recommended by other authors.^{4,21,22,24} This approach could be enough for most patients, but in the relevant number of recent-onset episodes of atrial fibrillation, a sinus-rhythm restoration attempt should be performed if spontaneous conversion did not happen after a period of observation (without prolonging the limit of 48 hours from the beginning of the episode), principally in patients without structural heart disease,^{4-6,19,20,24} taking advantage of the greater possibilities of achieving sinus rhythm in this population.

In conclusion, our study reveals a high frequency of ED attendance by patients with atrial fibrillation, and no management strategy for the arrhythmia is performed in most cases. Rate-control effectiveness is poor, rhythm control is not attempted in most eligible patients despite the high effectiveness noted, and DC cardioversion remains anecdotal in our series. Therefore, methods to improve rate-control effectiveness

(increasing the use of β -blockers and calcium blockers), the selection of patients with recent-onset episodes for rhythm control, and the use of electrocardioversion in this routine practice setting appear warranted.

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Author contributions: CA, AM, PL, and PG conceived and designed the study. AM supervised the conduct of the study and the data collection and was responsible for the design and codification of the data-collection sheet. CA provided statistical advice on study design and the data analyses. CA, AM, and PL drafted the manuscript and take responsibility for the paper as a whole.

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Address for correspondence: Alfonso Martín, MD, Emergency Department, Hospital de Móstoles, c/Río Júcar s/n, 28935-Móstoles, Madrid, Spain; 34-91-664-87-07, fax 34-91-664-87-65; E-mail amm002@wanadoo.es.

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Appendix. Members of the Atrial Fibrillation in Emergency Medicine Study Group (GEFAUR), Arrhythmia Division, Scientific Committee, Spanish Society of Emergency Medicine (SEMES), Madrid, Spain.

Chair: Alfonso Martín, MD, Arrhythmia Division SEMES and Hospital de Móstoles.

Coordination committee: Pedro Laguna, PhD, Arrhythmia division SEMES and HU Puerta Hierro; Carmen del Arco, PhD, Arrhythmia division SEMES and HU Princesa; and Pedro Gargantilla, MD, Arrhythmia division SEMES and H El Escorial.

Investigators and participating institutions: José F. Perianes, MD, José F. Hoyo, MD, Mar Laínez, MD, Gabriel Martínez, MD, Abel Ovejero, MD, Hermenegildo Matamoros, MD, Óscar Álvarez, MD, Luis Martínez, MD, Fátima Fernández, MD, Alfonso Martín, MD, Hospital Móstoles; Tomas Isasia, MD, Ana Amengual, MD, José Ruiz, MD, Manuel Junquera, MD, Alberto Pizarro, MD, Pilar Sánchez, MD, Carmen del Arco, MD (HU Princesa); Manuel Moya, PhD, Rosario Salgado, MD, Sergio Calabrese, MD, Jorge Marrero, MD, José Gómez, MD, Carlos Mascías, MD, Pedro Laguna, PhD (HU Puerta Hierro); Juan Hinojosa, MD, Raquel Lana, MD, Juan Algarra, MD, Pedro Villarroel, MD (HU San Carlos); José Martín, MD (HU Ramón y Cajal); Miguel Mariné, MD, Pedro Gargantilla, MD (H El Escorial); Salvador Juárez, PhD (HU La Paz); Silvio Guardiola, MD, Javier Esteban, MD, Gloria Pérez, MD (HU Getafe); Javier Ortiz, MD (HU Gregorio Marañón); Carmen Perpiñá, MD, Nemesio Torres, MD (HU 12 Octubre); Carmen Mainez, MD, Lourdes Mancebo, MD, Santiago Artillo, MD, José Bascuñana, MD, Cristina Ancos, MD, Maria J. Sanz, MD, Elena Ortiz, MD, Elena Bello, MD (Hospital Severo Ochoa); and Belén Rodríguez, MD, Ana Ocaña, MD, Sonia Gonzalo, MD (FH Alcorcón).