A Prospective, Randomized Trial of an Emergency Department Observation Unit for Acute Onset Atrial Fibrillation

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Study objective: An emergency department (ED) observation unit protocol for the management of acute onset atrial fibrillation is compared with routine hospital admission and management.

Methods: Adult patients presenting to the ED with atrial fibrillation of less than 48 hours’ duration without hemodynamic instability or other comorbid conditions requiring hospitalization were enrolled. Participants were randomized to either ED observation unit care or routine inpatient care. The ED observation unit protocol included pulse rate control, cardiac monitoring, reassessment, and electrical cardioversion if atrial fibrillation persisted. Patients who reverted to sinus rhythm were discharged with a cardiology follow-up within 3 days, whereas those still in atrial fibrillation were admitted. All cases were followed up for 6 months and adverse events recorded.

Results: Of the 153 patients, 75 were randomized to the ED observation unit and 78 to routine inhospital care. Eighty-five percent of ED observation unit patients converted to sinus rhythm versus 73% in the routine care group (difference 12%; 95% confidence interval [CI] –1% to 25%; P=.06). The median length of stay was 10.1 versus 25.2 hours (difference 15.1 hours; 95% CI 11.2 to 19.6; P<.001) for ED observation unit and inhospital care respectively. Nine ED observation unit patients required inpatient admission. Eleven percent of the ED observation unit group had recurrence of atrial fibrillation during follow-up versus 10% of the routine inpatient care group (difference 1%; 95% CI −9% to 11%; P=.93). There was no significant difference between the groups in the frequency of hospitalization or the number of tests, and the number of adverse events during follow-up was similar in the 2 groups.

Conclusion: An ED observation unit protocol that includes electrical cardioversion is a feasible alternative to routine hospital admission for acute onset of atrial fibrillation and results in a shorter initial length of stay. [Ann Emerg Med. 2008;52:322-328.]
Editor’s Capsule Summary

What is already known on this topic
Hospital admissions for atrial fibrillation have increased by 66% during the past 2 decades, primarily because of the rapidly growing elderly population.

What question this study addressed
This 153-patient randomized trial compared observation unit care that included early cardioversion with routine hospitalization in patients with uncomplicated atrial fibrillation of less than 48 hours’ duration.

What this study adds to our knowledge
Patients treated in the observation unit had substantially shorter hospitalizations and were 12% (95% confidence interval –1% to 25%) more likely to be discharged in sinus rhythm.

How this might change clinical practice
Early cardioversion in the emergency department or observation unit may be a feasible alternative to hospitalization in patients with uncomplicated atrial fibrillation of short duration.

INTRODUCTION

Background

The prevalence of atrial fibrillation in the US population is currently estimated to be 2.3 million and will continue to increase as the population ages. By 2050, it has been projected that the prevalence of atrial fibrillation will be greater than 5.6 million. The incidence of new onset atrial fibrillation increases with age and is about 1% in persons aged 60 to 68 years, increasing to almost 5% in persons older than 69 years. During the past 20 years, hospital admissions for atrial fibrillation have increased by 66% primarily because of the rapidly growing elderly population.

Importance

Atrial fibrillation is a significant contributor to national health care expenditures. In 2005, total annual costs for treatment of atrial fibrillation were estimated at $6.65 billion, including hospitalizations, with a principal discharge diagnosis of atrial fibrillation ($2.93 billion), inpatient cost of atrial fibrillation as a comorbid diagnosis ($1.95 billion), outpatient treatment of atrial fibrillation ($1.53 billion), and prescription drugs ($235 million).

Diagnosis and appropriate management of this increasingly prevalent heart arrhythmia are critical because of its complication of heart failure and stroke, which may result in high levels of functional debility or death. The presence of atrial fibrillation confers a 5-fold increased risk of stroke. It is estimated that 15% of all strokes may be directly attributable to atrial fibrillation. Also of concern is that a stroke episode resulting from a cause of atrial fibrillation has a worse outcome in comparison with strokes of other origin. The Framingham Study has revealed a 1.5 to 1.9-fold higher risk of death associated with chronic atrial fibrillation, attributable largely to thromboembolic stroke. Studies have been done suggesting that emergency department (ED) observation unit care is a feasible option in patients with acute onset atrial fibrillation in whom initial ED stabilization has been achieved. Because current American Heart Association practice guidelines for the treatment of patients with atrial fibrillation do not advise routine anticoagulation in atrial fibrillation of less than 48 hours’ duration (or transesophageal echocardiograph) before cardioversion, there is an opportunity for definitive treatment in the ED for these patients.

Goals of This Investigation

Our study randomized patients with acute onset atrial fibrillation presenting to the ED to the observation unit with electrical cardioversion versus routine inpatient admission to compare outcomes in care.

MATERIALS AND METHODS

Setting

This prospective randomized study was performed during a period of 3 years (September 1999 to December 2002) in the ED of a tertiary referral center and was approved by the authors’ institutional review board.

Study Design

Only patients willing and able to sign an informed consent were included in this study. After granting consent, participants were randomized by telephone call to a remote, designated randomization center uninvolved in the patients’ care. Patients were then managed per the protocol to either care in the ED observation unit or routine inpatient hospital care (Figure 1).

Selection of Participants

Our cohort consisted of adult patients older than 18 years who presented to the ED of a tertiary referral center with atrial fibrillation of less than 48 hours’ duration, without hemodynamic instability or other conditions requiring hospitalization. Only patients from the 10 local counties served by the institution were enrolled to ensure comprehensive follow-up and minimize selection bias. Less than 48 hours’ duration was established from patient history of onset of symptoms, and any uncertainty in duration was a criterion for exclusion.

Exclusion criteria for the study included atrial fibrillation of greater than 48 hours’ duration and hemodynamic instability. Those patients presenting with an unclear duration of symptoms were presumed to have had them greater than 48 hours. Hemodynamic instability was defined as any patient with...
a systolic blood pressure less than 90 mm Hg, diastolic less than 50 mm Hg, or a pulse rate of 130 beats/min or more after attempts to rate control. Known intracardiac thrombus, class IV congestive heart failure, ejection fraction less than 30%, chest pain consistent with class IV angina, acute myocardial infarction within 4 weeks before atrial fibrillation onset, stroke or transient neurologic ischemic attack in the past 3 months, previous unsuccessful electrical cardioversion of atrial fibrillation or active medical problems other than atrial fibrillation such as unstable angina, pneumonia, transient neurologic ischemic attacks, and strokes requiring inpatient evaluation were also excluded from this study. Patients from outside of Olmsted County or its surrounding 9 counties were not eligible for enrollment.

Interventions and Methods of Measurement
The 8-hour ED observation unit protocol included recording of an ECG, chest radiograph, and routine laboratory investigations, including electrolyte levels, CBC count, and glucose level. This was followed by pharmacologic pulse rate control using a calcium channel blocker or a $\beta$-blocker. Rate control was defined as a ventricular response less than 100 beats/min at rest. All patients received continuous cardiac monitoring and were reassessed after 6 hours. Those still in atrial fibrillation were sedated and electrically cardioverted with the PhysioLifepak 6 (Medtronic Inc., Minneapolis, MN) (before 2001) or the Zoll M Series Biphasic Manual device (Zoll Medical Corporation, Burlington, MA) (after 2001) for correction of atrial fibrillation and observed for a further period of 2 hours. Those in sinus rhythm after the 2-hour observation period were discharged home, with cardiology follow-up arranged within 3 days. Patients who were enrolled in the study in the evening were observed overnight and cardioverted between 7 and 9 AM. Study patients treated in the ED observation unit were not given any antiarrhythmic on discharge and were not anticoagulated. Those remaining in atrial fibrillation after unsuccessful attempts to electrically cardiovert were admitted to the hospital cardiology service. All care, including initial evaluation, ED observation unit care, procedural sedation, and cardioversion, was overseen by the emergency medicine attending physician on duty.

The patients randomized to routine hospital care underwent an ECG and routine laboratory investigations in the ED. They were given an intravenous calcium channel blocker or a $\beta$-blocker for rate control, began receiving a heparin infusion, and were admitted to a monitored bed on the cardiology service. ED management was at the discretion of the emergency medicine attending physician on duty.

Follow-up for recurrence of atrial fibrillation, adverse events, and further visits to the hospital was performed during a 6-month period. We used telephone follow-up, in addition to record review. The patients were contacted at 30 days and 6 months, and no patients were lost to follow-up.

Outcome Measures
The primary endpoint was conversion to sinus rhythm or rate control at the completion of initial ED observation unit or hospital stay. Secondary endpoints were recurrence of atrial fibrillation and adverse events (subsequent myocardial infarction, congestive heart failure, stroke, or death). Further utilization of health care resources was measured by further recurrent visits to the hospital. All secondary endpoints were recorded during a 6-month follow-up period.

Primary Data Analysis
Factors were summarized with percentages, means, medians, and standard deviations, depending on the type of variable of interest (using SAS software, version 8.2; SAS Institute, Inc., Cary, NC). Categorical factors were compared between the groups by using the $\chi^2$ test for independence. For each of the continuous measurements, there was evidence that the values were nonnormal, so the comparisons between the groups were carried out with the Wilcoxon rank-sum tests for each of the measurements. A $P<.05$ was considered to be significant.

RESULTS
Characteristics of Study Subjects
Throughout the 39-month study period, 252,392 patients presented to the ED; 2,096 of these patients were found to have atrial fibrillation, and 153 patients were eligible and enrolled to this study after written consent was obtained. Seventy-five of the 153 patients were randomized to the ED observation unit and 78 to routine inpatient hospital care (Figure 2). Reasons for exclusion and number of patients excluded are outlined in Table 1. The average age of the patients admitted to the ED observation unit was 58±18 years, and 53% were men, whereas the average age of the inpatient service group was 59±16 years, of whom 69% were men. Table 2 shows demographic characteristics of the study population.
Main Results

Of the 2 groups, 85% (64) converted to normal sinus rhythm in the ED observation unit cohort compared with 73% (57) in the routine care group ($P = 0.06$, $\chi^2$ test; difference $=12$%; 95% CI $= 1$% to 25%) (Table 3). The median length of stay for the ED observation unit set was 10.1 hours and mean 12.6 hours, whereas the median and mean length of stay for admitted patients was 25.2 hours and 50.1 hours, respectively ($P < .001$, rank-sum test; difference in medians is $=15.1$; 95% CI $= 11.2$ to 19.6). Among the cases randomized to the ED observation unit, 24 (32%) reverted to normal sinus rhythm after pharmacologic rate control and 38 (51%) required electrical biphasic cardioversion (Table 4).
Conversion to Calcium channel Recurrent atrial Outcome (6 mo) Digoxin 4 (5) 6 (8) Recurrent visit 25 (33) 27 (35) Death 0 0 Stroke 0 0 Congestive heart failure 0 0 Myocardial infarction 0 1 (1)

Mean number of care group (fibrillation in comparison with 10% (8) of the routine inpatient ED observation unit group had recurrence of atrial instability after successful cardioversion. Two patients denied increased cardiac marker levels and 1 because of hemodynamic electrical cardioversion, whereas 2 were admitted because of patients had recurrent atrial fibrillation after an attempt at admission after the 8-hour observation period. Four of these failed to meet the criteria for discharge and required inpatient procedures at 6 mo (median)

Mean number of health care visits (median) 2.9 (3.0) 2.9 (3.0) 0 (−0.6 to 0.5)

Table 4. Management and outcome between the ED observation unit and inpatient groups.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>ED Observation Unit Group (%)</th>
<th>Inpatient Group (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrical cardioversion</td>
<td>38 (51)</td>
<td>18 (23)</td>
</tr>
<tr>
<td>Spontaneous conversion after rate control</td>
<td>24 (32)</td>
<td>34 (44)</td>
</tr>
<tr>
<td>Rate-controlling agents</td>
<td></td>
<td></td>
</tr>
<tr>
<td>β-Blocker</td>
<td>15 (20)</td>
<td>27 (35)</td>
</tr>
<tr>
<td>Calcium channel blockers</td>
<td>56 (75)</td>
<td>57 (73)</td>
</tr>
<tr>
<td>Digoxin</td>
<td>4 (5)</td>
<td>6 (8)</td>
</tr>
<tr>
<td>Outcome (6 mo)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recurrent atrial fibrillation</td>
<td>8 (10)</td>
<td>8 (10)</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>0</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Stroke</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Recurrent visit</td>
<td>25 (33)</td>
<td>27 (35)</td>
</tr>
</tbody>
</table>

Twenty-four patients underwent spontaneous/nonelectrical conversion from the ED observation unit group, as did 34 patients in the inpatient group. The remaining cases (N=9) failed to meet the criteria for discharge and required inpatient admission after the 8-hour observation period. Four of these patients had recurrent atrial fibrillation after an attempt at electrical cardioversion, whereas 2 were admitted because of increased cardiac marker levels and 1 because of hemodynamic instability after successful cardioversion. Two patients denied ED observation unit care and requested admission after randomization.

During follow-up within 6 months of the study, 11% (8) of the ED observation unit group had recurrence of atrial fibrillation in comparison with 10% (8) of the routine inpatient care group (P=.93, χ² test; difference in percentages 1%; 95% CI of the differences −9% to 11%). There were no significant differences between the groups in the frequency of hospitalization, number of tests/procedures, or adverse events during their 6-month follow-up (Tables 3, 4). No patients were lost to follow-up.

LIMITATIONS

The limitations involve the sample size at a single center, which may limit the ability to generalize to other patient populations. Sample size also makes it difficult to assess the risk of stroke and other major complications. Further, no distinction was made between new and recurrent atrial fibrillation and the various underlying causes of atrial fibrillation. This reflects the investigators’ desire to develop a protocol for most acute onset atrial fibrillation patients, but we recognize there are some subtle differences in these groups. A significant difference in sex between the cohorts was observed with more women in the ED observation unit group. The sex-related difference in the Rate Control versus Electrical Cardioversion (RACE) study showed that women were more likely to have a poorer outcome in the rhythm control treatment of persistent atrial fibrillation. But no disparity in outcome was observed between the groups despite the difference in distribution. Also, treatment of the patients in the inpatient arm was not standardized and was up to the discretion of the cardiologist.

DISCUSSION

ED observation units have been described as a rational choice for improving the utilization of health care resources and improving the quality of patient care. They have been used successfully in the treatment of common conditions such as chest pain, asthma, and syncope and have been suggested for atrial fibrillation. We sought to determine the benefit of observation unit management of atrial fibrillation, an increasingly prevalent condition, over traditional inpatient care.

Our study showed that the management of acute onset atrial fibrillation of less than 48 hours’ duration in the ED observation unit was comparable to inpatient care with regard to rhythm conversion and recurrence of atrial fibrillation and adverse events (subsequent myocardial infarction, congestive heart failure, stroke, or death). Though fewer patients received electrical cardioversion in the inpatient arm, the overall conversion rates were comparable. This may also be due to a function of time. ED observation unit care resulted in a shorter hospital length of stay, without any change in overall utilization of health care visits during the 6 months after enrollment.

Much attention has been given to the rate versus rhythm control strategies for chronic atrial fibrillation. The Atrial Fibrillation Follow-up Investigation of Rhythm Management (AFFIRM) and RACE studies, which included patients with longstanding atrial fibrillation, showed no significant difference in survival or quality of life with rate control compared with a rhythm control strategy. Most patients who experienced strokes in AFFIRM were not treated with warfarin or had a subtherapeutic international normalized ratio at the stroke, and more patients in the rhythm control arm had warfarin.
There was also a significant increase in fatal noncardiovascular events in the rhythm control arm in contrast to rate control.\textsuperscript{19} This was suggested to be due to the increased use of amiodarone for rhythm control, which has been shown to increase noncardiovascular mortality.\textsuperscript{19} But both of the above studies did not examine a population with atrial fibrillation of less than 48 hours’ duration. With prolonged atrial fibrillation, there is difficulty in restoring sinus rhythm because of electrical and structural remodeling of the heart, which favors permanent atrial fibrillation. This makes it important to ensure that an attempt is made to restore sinus rhythm early in the course of treatment of a patient with atrial fibrillation.\textsuperscript{9}

Cardioversion performed early after admission can successfully restore a sinus rhythm in most patients. A retrospective study done in 2005 suggested that shorter duration of atrial fibrillation (<48 hours) and absence of heart failure are reliable predictive factors of a successful conversion to sinus rhythm.\textsuperscript{20} A similar prospective cohort study that used ibutilide and cardioversion in the ED for patients with atrial fibrillation less than 48 hours’ duration had results comparable to our data with respect to conversion to sinus rhythm.\textsuperscript{2} Our trial encompassed a larger cohort and was controlled to compare the efficacy of treatment. Earlier studies have also likewise concluded that most patients with recent onset atrial fibrillation who undergo successful ED electrical cardioversion do not appear to require admission to the hospital and that immediate and short-term complications were relatively uncommon.\textsuperscript{22,23} In a prospective cohort of 1822 patients, Weigler et al\textsuperscript{24} found that the likelihood of clinical thromboembolism is 0.8% among patients with atrial fibrillation lasting less than 48 hours who convert to sinus rhythm, which supports the recommendation for early cardioversion in these patients.

Atrial fibrillation is a significant contributor to health care costs. Approximately 350,000 hospitalizations each year are attributable to atrial fibrillation in the United States. Total annual costs for treatment of atrial fibrillation are estimated at $6.65 billion, including $2.93 billion for hospitalizations with a principal discharge diagnosis of atrial fibrillation.\textsuperscript{4} Therefore, an ED observation unit management approach would play a part in reducing the annual national expense in the management of atrial fibrillation.

During the past 20 years, there has been a 66% increase in hospital admissions for atrial fibrillation\textsuperscript{2} because of a combination of factors, including the aging of the population, an increasing prevalence of chronic heart disease, and more frequent diagnosis through use of ambulatory monitoring devices. Atrial fibrillation is a costly public health problem, with hospitalizations as the primary cost driver.\textsuperscript{16} Considering the mean number of admissions per year, initiating ED observation unit admission and management would potentially decrease the number of beds occupied on the wards, thus increasing the availability of beds.\textsuperscript{25}

Costs of care throughout the RACE study were comparable for the rhythm control, as well as for the rate control group, at the end of the follow-up period.\textsuperscript{26} Hence, an ED observation unit approach with adequate rate control in the ED setting might provide comprehensive management with a lower expenditure rate for a patient with new onset atrial fibrillation, considering the absence of comorbid conditions, acute onset, and low risk of thromboembolism.\textsuperscript{8} Few prospective data are available on the management of atrial fibrillation in the ED. A retrospective study done in 1996 showed 216 patients admitted for atrial fibrillation, of which 66% met predetermined admission criteria. Their criteria for a medically justified admission included variables recorded in the ED on presentation (hypotension with a systolic blood pressure <90 mm Hg; presence of comorbid condition in addition to atrial fibrillation that warranted admission, such as congestive heart failure, myocardial infarction, and significant complication during ED; or inpatient stay).\textsuperscript{27}

The benefits of our study include its prospective randomized nature and similarity of the groups. Inclusion of patients from only the local counties helped minimize referral bias. Thus, there might be a large number of patients eligible from outside the local counties, and our tertiary practice may have underestimated the eligible patients presenting to community hospitals.

Ideally, this study would be followed by a multicenter trial with larger patient numbers as we would like assess generalizability. We used both monophasic and biphasic defibrillators in our trial because biphasic units were just being introduced during our study. We would have preferred to use biphasic defibrillating pulse waveforms throughout the study. Improved success rates of biphasic over monophasic defibrillators have been published by Greene et al.\textsuperscript{28}

The data suggest that atrial fibrillation management guidelines for new onset atrial fibrillation should perhaps be revisited to include an ED observation unit as an alternative to inpatient admission in selected patients presenting with acute onset atrial fibrillation. Such a protocol may reduce hospital stay and annual expenditure for this increasingly prevalent condition while maintaining the same quality and outcome of care.

In summary, an ED observational unit protocol with rate control and electrical cardioversion capabilities is a feasible alternative to inhospital admission of acute onset atrial fibrillation presentations of less than 48 hours’ duration. A multicenter trial would be helpful to assess the safety of this approach.

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**REFERENCES**


