Published in final edited form as:

J Cardiovasc Electrophysiol. 2011 May ; 22(5): 548–553. doi:10.1111/j.1540-8167.2010.01950.x.

Trends in U.S. Hospitalizations Rates and Rhythm Control Therapies Following Publication of the AFFIRM and RACE Trials

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Abstract

Introduction—The impact of trials comparing rate vs. rhythm control for AF on subsequent use of rhythm control therapies and hospitalizations at a national level has not been described.

Methods and Results—We queried the Healthcare Cost & Utilization Project on the frequency of hospital admissions and performance of specific rhythm control procedures from 1998–2006. We analyzed trends in hospitalization for AF as principal diagnosis before and after the publication of key rate vs. rhythm trials in 2002. We also reviewed the use of electrical cardioversion and catheter ablation as principal procedures during hospital admissions for any cause and for AF as principal diagnosis. We additionally appraised the overall outpatient utilization of antiarrhythmic drugs during this same time frame using IMS Health's National Prescription Audit.TM Admissions for AF as a principal diagnosis increased at 5%/year from 1998–2002. Following publication of the AFFIRM and RACE trials in 2002, admissions declined by 2%/year from 2002–2004, before rising again from 2004–06. In-hospital electrical cardioversion followed a similar pattern. National prescription volumes for antiarrhythmic drugs grew at <1%/yr from 2002–06, with a marked decline in the use of Class I-A agents, while catheter ablations during admissions for AF as the principal diagnosis increased at 30%/year.

Conclusion—The use of rhythm control therapies in the U.S. declined significantly in the first few years after publication of AFFIRM and RACE. This trend reversed by 2005, at which time rapid growth in the use of catheter ablation for AF was observed.

Keywords

Atrial fibrillation; catheter ablation; AFFIRM; RACE; antiarrhythmic drug; cardioversion

INTRODUCTION

Atrial fibrillation (AF) is the most common cause of arrhythmia-related hospitalization.¹ Hospitalizations account for roughly 50% of AF-related direct medical care costs,^{2,3} and the

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number of U.S. hospitalizations for AF has grown dramatically, approximately tripling between 1985 and 1999.^{4,5} Cardiovascular hospitalization has been proposed as a surrogate marker for mortality in AF studies,⁶ and this endpoint has recently been employed in AF clinical research, with the U.S. FDA approving a new antiarrhythmic drug specifically to reduce the risk of cardiovascular hospitalization in AF in 2009.⁷ However, the “need” for hospitalizing AF patients may depend on many factors, including habits, fiscal incentives, local practice environments, and physician and patient attitudes toward rhythm control therapies.

To address questions about the optimal management strategy for AF, several major pharmacologic “rate vs. rhythm” randomized controlled trials were conducted, including the AFFIRM⁸ and RACE⁹ trials. Results for both AFFIRM and RACE were published in December 2002, and the trials found that rhythm control with antiarrhythmic drugs and cardioversions offered no survival advantages over rate control.

However, the full impact of the AFFIRM and RACE trials on AF management in the U.S. are not fully understood. The effect of these trials on subsequent utilization of rhythm control therapies and hospitalizations for AF has not been explored at a national level over time. Therefore, we chose to examine four aspects of AF management that might be affected by attitudes toward rhythm control versus rate control: hospitalization, cardioversion, antiarrhythmic drug prescription, and catheter ablation.

METHODS

Data sources

Two longitudinal, nationally representative databases were used: HCUPNet (accessed at <http://hcupnet.ahrq.gov/>), a free online query system that is based on the Healthcare Cost and Utilization Project’s (HCUP) Nationwide Inpatient Sample (NIS) database (1998–2006); and IMS Health’s National Prescription AuditTM (1998–2006).

Identification of AF-Related Hospitalizations and Rhythm Control Procedures

The HCUP’s NIS contains claims-based hospital discharge data from a 20% sample of U.S. short-stay, non-federal hospitals.¹⁰ The universe of sampled hospitals represents approximately 90% of the U.S. population. In 1998, 22 states contributed data to the NIS, from 984 hospitals with 6.8 million admissions; these numbers increased to 38 states, 1,045 hospitals, and 8.1 million admissions in 2006.¹¹ The hospital sampling frame is defined as community hospitals (including public hospitals, academic medical centers and specialty hospitals) that were open during any part of the calendar year. Each hospital stay record contains: patient age, sex, principal and comorbid discharge diagnoses, principal and secondary medical or surgical procedures/tests, payer, length of stay, and total billed charges. HCUPNet provides national estimates for diagnoses and procedures based on the NIS and other databases from the HCUP¹². Weights are calculated to project representative national estimates. HCUPNet is searchable by diagnosis or procedure code for each calendar year at state and national levels.

Identification of AF-related hospitalizations was based on the designation of the International Classification of Diseases (9th Edition)—Clinical Modification (ICD-9-CM) diagnosis code 427.31 (atrial fibrillation) as the principal discharge diagnosis. Hospitalizations with AF as the principal diagnosis were also stratified according to patient and hospital characteristics, including patient age, payer, hospital teaching status, and hospital location (metropolitan vs. non-metropolitan). Identification of inpatient electrical cardioversions was based on the ICD-9-CM procedure codes 99.61 (atrial cardioversion), 99.62 (other electric countershock of heart), or 99.69 (other conversion of cardiac rhythm)

as the principal procedure during admissions both for any principal diagnoses and for AF (427.31) as the principal diagnosis. Likewise, identification of inpatient catheter ablations was based on the ICD-9-CM procedure code 37.34 (catheter ablation of lesion or tissues of heart) as the principal procedure both for any principal diagnoses and for AF (427.31) as the principal diagnosis. These data were queried for all years from 1998 to 2006. Data were only available from 2001 to 2006 on principal procedure electrical cardioversions and catheter ablations that had AF as the principal diagnosis. Principal procedure electrical cardioversions and catheter ablations for all other principal diagnoses were calculated by subtracting principal procedures that had AF as the principal diagnosis from total principal procedures for all diagnoses, from 2001 to 2006.

Identification of Oral Antiarrhythmic Drug Prescription Patterns

Data on oral antiarrhythmic drug prescriptions were provided by IMS Health, a commercial vendor of prescription drug information, from the National Prescription Audit™ (NPA).¹³ The National Prescription Audit™ consists of data from a panel of 37,000 stores that account for more than half of all retail pharmacies in the United State, as well as ~100 mail order pharmacies, in total representing approximately 74% of retail prescription volume and 60–80% of mail order prescription volume in the U.S. Data is then projected to provide a national estimate for total dispensed prescriptions.

Information was provided from the NPA for oral agents from the following Vaughn-Williams drug classes: Class IA (procainamide, quinidine, disopyramide); Class IC (flecainide, propafenone); and Class III (amiodarone, sotalol, dofetilide). Definition of this set of drugs was provided to IMS Health by the authors. Data was extracted on June 3, 2010. Descriptive statistics were used to report on the number of total dispensed prescriptions from retail and mail order pharmacies of oral antiarrhythmic drugs during the time period from January 1998 to December 2006.

Compound annual growth rates for the number of hospitalizations, procedures, and prescriptions were calculated in Microsoft Excel, using the following formula: $CAGR = (Value_{final}/Value_{initial})^{(1/Years)} - 1$.

RESULTS

HCUP Nationwide Inpatient Sample

The number of U.S. hospitalizations with AF as the principal diagnosis increased at a compound annual growth rate (CAGR) of 5% per year between 1998 and 2002 (Table 1). Following publication of the AFFIRM and RACE results in December 2002, this increasing trend reversed for the next 2 years, and AF-principal diagnosis admissions declined at a 2002–2004 CAGR of –2% per year, before increasing again from 2004 to 2006 at a CAGR of 7% per year.

In addition to changes in the total number of hospitalizations with AF as the principal diagnosis, the source of admissions for these hospitalizations also changed between 1998 and 2006 (Figure 1). Emergency department admissions with AF as the principal diagnosis increased from 57% of the total in 1998 to 63% in 2006, while elective admissions with AF as the principal diagnosis declined from 40% of the total to 33% over the time period. As shown in Figure 2, after the publication of AFFIRM and RACE in 2002, growth declined in both elective admissions and emergency department admissions with AF as the principal diagnosis, but elective admissions declined at greater rates.

Hospitalizations with AF as the principal diagnosis were examined by patient and hospital characteristics (Figure 3) to determine whether overall trends were driven by changes in

particular patient populations or hospital types. The majority of hospitalizations with AF as the principal diagnosis occurred in patients between the ages of 65 and 85, and between 2001 and 2004 hospitalizations in this age group also decreased more than in other age groups (Figure 3A). By payer, Medicare beneficiaries accounted for more than half of all hospitalizations (Figure 3B). While there were more total hospitalizations with AF as the principal diagnosis in nonteaching hospitals over the time period, growth occurred only in the teaching hospital segment between 2002 and 2006, particularly in the last year of the period, while the number of hospitalizations in nonteaching hospitals remained stable (Figure 3C). There were also qualitative differences observed for hospitalizations at metropolitan compared to non-metropolitan hospitals, with growth observed at metropolitan hospitals between 2004 and 2006, and no change at non-metropolitan hospitals (Figure 3D).

Trends in principal procedure electrical cardioversions were also examined from 2001 to 2006. Cardioversions both with AF as the principal diagnosis and with all other principal diagnoses declined from 2001 to 2004, after which the number of cardioversions with AF as the principal diagnosis resumed positive growth in 2005 and 2006, while cardioversions for all other principal diagnoses stabilized (Figure 4). Principal procedure cardioversions in which AF was the principal diagnosis accounted for somewhat more than half of all cardioversions, and the trend in cardioversions with AF as the principal diagnosis paralleled changes in total cardioversions over the time period (Table 1).

As opposed to the decline in principal procedure cardioversions, principal procedure catheter ablations showed large increases during the study period (Figure 4). Between 2001 and 2006, principal procedure catheter ablations with AF as the principal diagnosis grew at a CAGR of 30% per year, and principal procedure catheter ablations for all other principal diagnoses grew at a CAGR of 12% per year.

IMS National Prescription Audit™

Between 1998 and 2002, the number of oral antiarrhythmic drug (AAD) prescriptions for all diagnoses dispensed from U.S. retail and mail order pharmacies grew at a CAGR of 3% per year (Table 2, Figure 5). This rate of increase slowed to a CAGR of less than 1% per year between 2002 and 2006. All of this moderate increase seen in total prescriptions between 2002 and 2006 was observed entirely during the last year of the period, as the number of total AAD prescriptions was nearly unchanged between 2002 and 2005.

Greater changes were observed in the use of different classes of AADs than in total AAD usage, with prescriptions for Class IA agents declining significantly between 1998 and 2006, at a CAGR of -21% per year. In contrast, prescriptions for other Vaughn-Williams drug classes grew during the time period, with prescriptions for Class IC agents (propafenone and flecainide) increasing at a 3% CAGR, and prescriptions for Class III agents (amiodarone, sotalol, and dofetilide) initially growing rapidly at a 16% per year from 1998 to 2002, then from 2002 to 2006 at a more moderate rate of 3% per year. Amiodarone accounted for 60% of Class III prescriptions in 2006, and drove a significant amount of Class III prescription growth between 1998 and 2006.

DISCUSSION

In this study of U.S. hospitalization rates and AF rhythm control treatment patterns over time, significant changes were observed in the years following the 2002 publication of the AFFIRM and RACE trials. Reversing a previously reported,⁵ prolonged trend that continued from 1998–2002, hospitalizations with AF as the principal diagnosis declined at a rate of 2% per year from 2002 to 2004, in parallel with a decline in electrical cardioversions. Hospitalization rates began increasing again in 2005 and 2006, during which time robust

growth was observed in catheter ablations with AF as the principal diagnosis. Given that catheter ablation for patients with a diagnosis of AF is performed significantly more frequently at hospitals with larger bed-sizes,¹⁴ it is of interest that the increase in AF hospitalization rates in 2005 and 2006 was observed primarily at teaching and metropolitan hospitals. Outpatient use of oral antiarrhythmic drugs also changed during this timeframe, with the number of prescriptions plateauing from 2002 to 2005 after a period of sustained growth between 1998 and 2002.

The current data extend previously documented increases in the number of hospitalizations for AF^{4,5} and AF catheter ablations,^{14,15} as well as previously observed prescription growth for Class IC and Class III AADs and declining use of Class IA AADs.^{16,17} This study expands on historical trends by providing information on how these AF management patterns were affected following the publication of AFFIRM and RACE. The current data show a clear change in AF hospitalizations and rhythm control treatment patterns following the publication of AFFIRM and RACE in 2002. In particular, elective admissions for AF management and utilization of inpatient cardioversion declined from 2002–04.

Some of our findings, particularly those related to antiarrhythmic drug utilization, are similar to those reported by the Euro Heart Survey^{18,19} and the RecordAF^{20,21} AFFECTS registries.²² However, these registries were primarily cross-sectional in nature and therefore do not permit the longitudinal perspective contained in the current report.

Other observational databases have provided information on AF treatment patterns in the U.S. since AFFIRM and RACE, and suggest an impact of these trials on AF treatment patterns. Similar changes in Class IA, IC, and III antiarrhythmic drug prescriptions were reported between the 12-month periods ending June 2003 and June 2004.²³ In smaller observational studies from two university medical centers and in selected patient populations in isolated U.S. states or Canadian provinces, usage of both cardioversion and AADs was also reported to decline after the publication of AFFIRM and RACE.^{24,25} However, data are not available on whether these declines were temporary or sustained, nor is this information nationally representative. In addition, previous publications do not provide information on trends in AF hospitalizations following AFFIRM and RACE, yet hospitalization is the largest single driver of AF treatment cost.

Given the magnitude of AF hospitalization treatment costs, this post-AFFIRM/RACE decline in AF-related hospitalizations is intriguing not only from a clinical, but also from a health economic perspective. Analysis of the AFFIRM trial demonstrated that a rate control strategy was clinically equivalent (to marginally more effective) and significantly less costly than a rhythm control strategy using AADs.²⁶ Whether the apparent shift back towards rhythm control interventions seen in the later years of our analysis represents cost-effective care remains to be established.

The present data may also have implications for the use of hospitalization as an endpoint in AF clinical trials. Although post hoc analysis from the AFFIRM trial demonstrated that patients hospitalized during follow-up faced an increased risk of subsequent mortality,²⁷ there are potentially many factors that may influence the likelihood of AF hospitalizations, including the local availability of outpatient services, the financial incentives and disincentives of differing payment models, physician training and habits, and patient preferences and expectations. Our data suggest that patients and physician attitudes toward rhythm vs. rate control likely also influence hospitalization rates.

There are a number of limitations associated with this analysis. Given that NIS is based on claims data from a sampling of U.S. hospitals, figures for number of hospitalizations and procedures are necessarily estimates rather than exact counts. Since HCUPNet provided

information only on hospitalization and inpatient procedures, this study does not capture information on non-pharmacologic outpatient rhythm management of AF, and is therefore an incomplete picture of rhythm control treatment patterns. Some trends observed in inpatient treatment patterns may be related to shifting of care to the outpatient setting. There are no specific ICD-9 codes for AF ablation or AF cardioversion, complicating the estimation of the inpatient volume for these procedures. We therefore reported these principal procedures for any principal diagnosis of AF, but recognize that these designations may not always be accurate. We have not examined admission-level data to assess factors associated with these trends in a multivariate context. For IMS National Prescription Audit™ data, prescription data are not specific for the AF diagnosis, so total prescription numbers also represent use for other diagnoses in addition to AF, though we believe AF is the most common indication for each of these drug classes. Finally, our attribution of the temporal trends we observed to the AFFIRM and RACE trials is speculative. These observed changes cannot be attributed with certainty to the publication of AFFIRM and RACE, as multiple factors may drive changes in clinical practice, including the dissemination of other scientific evidence, commentary from opinion leaders, changing guidelines, media coverage, and various other factors.

CONCLUSION

This analysis shows that previously increasing trends in AF-related hospitalization and use of rhythm control strategies for AF declined following the publication of AFFIRM and RACE. Hospitalization for AF and use of rhythm control therapies appear to be influenced by attitudes and preferences for rate vs. rhythm control, which were affected by the results of AFFIRM and RACE.

Acknowledgments

Dr. Reynolds was supported in part by award K23 HL077171 from NHLBI. Dr. Essebag is the recipient of a Clinician Scientist Award from the the Canadian Institutes of Health Research (CIHR).

Dr. Reynolds has received research grants and consulting fees from Biosense Webster and Sanofi Aventis. Dr. Essebag has received honoraria from Biosense Webster, Sanofi Aventis, Medtronic Inc., & Bayer.

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Figure 1.
U.S. hospital discharges with AF as principal diagnosis, by source of admission, 1998–2006.

Figure 2.
Year-over-year change in U.S. hospital discharges with AF as principal diagnosis, by source of admission, 1998–2006.

Figure 3A

Figure 3C

Figure 3D

Figure 3. U.S. hospital discharges with AF as principal diagnosis, 1998–2006, stratified by patient and hospital characteristics. A: By patient age; B: By payer; C: By hospital teaching status; D: By hospital location.

Figure 4. U.S. principal procedure electrical cardioversions and catheter ablations with AF as the principal diagnosis and with all other principal diagnoses, 2001–2006.

Figure 5. Dispensed oral antiarrhythmic drug prescriptions through U.S. retail and mail pharmacies, 1998–2006. (Source: National Prescription Audit™, January 1998 – December 2006, IMS Health Incorporated. All Rights Reserved.)

Table 1

Number of hospitalizations with AF as principal diagnosis, principal procedure electrical cardioversions with AF as principal diagnosis, and principal procedure catheter ablations with AF as principal diagnosis, 1998–2006

	1998	1999	2000	2001	2002	2003	2004	2005	2006
Hospitalizations with AF as principal diagnosis	289,120	295,060	324,405	348,131	349,888	344,381	333,287	352,171	380,209
% change		2.1%	9.9%	7.3%	0.5%	-1.6%	-3.2%	5.7%	8.0%
Electrical cardioversions (principal procedure with AF as principal diagnosis)	N/A	N/A	N/A	38,798	34,786	30,145	27,325	30,107	32,183
% change					-10.3%	-13.3%	-9.4%	10.2%	6.9%
Catheter ablations (principal procedure with AF as principal diagnosis)	N/A	N/A	N/A	4,238	4,355	4,669	7,341	15,101	15,869
% change					2.8%	7.2%	57.2%	105.7%	5.1%

Source: HCUPNet, 1998–2006

Table 2

Total dispensed prescriptions for oral antiarrhythmic drugs through U.S. retail and mail pharmacies, 1998–2006 (Thousands)

	1998	1999	2000	2001	2002	2003	2004	2005	2006
Total	6,119	6,404	6,611	6,603	6,824	6,728	6,770	6,736	6,968
% change		4.7%	3.2%	-0.1%	3.3%	-1.4%	0.6%	-0.5%	3.4%
Class IA	2,372	1,926	1,519	1,125	889	693	537	438	369
% change		-18.8%	-21.1%	-25.9%	-21.0%	-22.0%	-22.5%	-18.4%	-15.8%
Disopyramide	549	487	429	355	307	260	227	195	173
Quinidine	1,258	993	750	539	418	321	229	182	150
Procainamide	564	447	340	231	164	112	82	60	46
Class IC	1,178	1,299	1,348	1,353	1,362	1,322	1,324	1,401	1,529
% change		10.3%	3.8%	0.4%	0.7%	-2.9%	0.2%	5.8%	9.1%
Propafenone	701	767	775	740	710	662	652	703	767
Flecainide	477	532	573	614	652	660	672	698	762
Class III	2,569	3,179	3,745	4,124	4,573	4,713	4,909	4,898	5,070
% change		23.7%	17.8%	10.1%	10.9%	3.1%	4.2%	-0.2%	3.5%
Amiodarone	1,647	2,058	2,412	2,625	2,907	3,007	3,128	3,026	3,066
Sotalol	922	1,121	1,323	1,453	1,575	1,598	1,653	1,721	1,826
Dofetilide	-	-	9	46	90	107	128	151	178

Source: National Prescription AuditTM, January 1998 – December 2006, IMS Health Incorporated. All Rights Reserved.