# Design and Results of the Antiarrhythmics vs Implantable Defibrillators (AVID) Registry

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**Background**—The Antiarrhythmics Versus Implantable Defibrillators (AVID) Study compared treatment with implantable cardioverter-defibrillators versus antiarrhythmic drugs in patients with life-threatening ventricular arrhythmias (VAs). AVID maintained a Registry on all patients, randomized or not, with any VA or unexplained syncope who could be considered for either of the treatment strategies. Trial-eligible arrhythmias were the categories of VF cardiac arrest, Syncopal VT, and Symptomatic VT, below.

Methods and Results—Of 5989 patients screened, 4595 were registered and 1016 were randomized. Mortality follow-up through 1996 was obtained on the 4219 Registry patients enrolled before 1997 through the National Death Index. Crude mortality rates (mean±SD, follow-up, 16.9±11.5 months) were: VF cardiac arrest, 17.0% (n=1399, 238 deaths); Syncopal VT, 21.2% (n=598, 127 deaths); Symptomatic VT, 15.8% (n=1065, 168 deaths); Stable (asymptomatic) VT, 19.7% (n=497, 98 deaths); VT/VF with transient/correctable cause, 17.8% (n=270, 48 deaths); and Unexplained syncope, 12.3% (n=390, 48 deaths).

Conclusions—Patients with seemingly lower-risk or unknown-risk VAs (asymptomatic VT, and VT/VF associated with a transient factor) have a (high) mortality similar to that of higher-risk, AVID-eligible VAs. The similar (and poor) prognosis of most patients with VT/VF suggests the need for reevaluation of a priori risk grouping and raises the question of the appropriate arrhythmia therapy for a broad range of patients. (Circulation. 1999;99:1692-1699.)

Key Words: antiarrhythmia agents ■ registries ■ death, sudden ■ fibrillation ■ tachycardia

R andomized trials comparing new and control (or standard) treatments provide the most accurate basis for statistical and clinical inferences about the utility of new therapies. Although randomization helps to ensure the internal validity of a trial, its external validity depends on how well the randomized patients represent the general population with the disease under consideration. That may be difficult to determine. Typically, only a minority of eligible patients enter randomized trials. In this regard, a registry of all patients presenting with the disease at the participating centers may be extremely informative. Not only can a registry address to what extent the enrolled study sample compares with the diseased population, but it also can provide information about the natural history of the disease in both eligible and noneligible patients. A well-designed and -maintained registry thus may provide critical information in evaluating to what extent the study results should be generalized and highlight areas in which additional investigation is needed.

Survivors of ventricular fibrillation (VF) or symptomatic, sustained ventricular tachycardia (VT) represent an important therapeutic target and public health problem¹ because of their known high risk of arrhythmia recurrence and sudden

death.<sup>2,3</sup> Traditional antiarrhythmic drugs have not provided effective prophylaxis against sudden death (even when guided by Holter recordings or electrophysiological studies) and have sometimes been harmful.<sup>4–7</sup> In the past few years, treatment for these patients has consisted mainly of the mixed class II/III agents amiodarone and sotalol or implantable cardioverter-defibrillators (ICDs).<sup>8–14</sup> Randomized trials comparing these therapies are only now being performed and results reported.<sup>15–21</sup> The Antiarrhythmics Versus Implantable Defibrillators (AVID) study was a large, randomized, secondary prevention trial.<sup>21</sup> In AVID, ICD therapy was associated with 39%, 27%, and 31% reductions in mortality at 1, 2, and 3 years, respectively, compared with antiarrhythmic drug therapy (mostly empirical amiodarone).

We present here the design and initial observations of the AVID Registry study, performed in parallel with the randomized trial. We confirm preliminary observations that the randomized patients are representative of the general highrisk VT/VF population.<sup>22</sup> Finally, we present clinical characteristics and survival for patients thought, at the time of trial design, to be at too low risk for arrhythmia recurrence to be included in the trial.

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<sup>\*</sup>AVID Investigators are listed in Appendix 2.

#### Index Arrhythmia Classification **AVID Registry**

#### Index Arrhythmia:

PRIMARY means there is no evidence (even weak) that the event was due to transient or correctable cause

(Check only one)

- (A) PRIMARY cardiac arrest due to VF
   (B) Documented sustained PRIMARY VT with syncope
- (C) Documented sustained PRIMARY VT, systolic BP <80 mmHg or chest pain or near-syncope AND FF <0.40
- (D) Documented sustained PRIMARY VT, systolic BP <80 mmHg or chest pain or near-syncope BUT EF >0.40
- (E) Documented sustained PRIMARY VT, hemodynamically stable
- (F) Out-of-hospital documented sustained VT or cardiac arrest due to VF associated with transient or

If (F) checked, indicate the most probable cause:

- (F 1) New O wave MI
- (F.2) New non-Q wave MI
- (F.3) Antiarrhythmic drug reaction
- (F.4) Electrolyte imbalance
- (F.5) Cocaine or other illicit drug
- (F.6) Other
- O (G) Out-of hospital syncope with structural heart disease and EP inducible VT/VF with symptoms

Figure 1. Registry checklist for classification of index arrhythmia as to cause, type, and associated symptoms. BP indicates blood pressure; EF, ejection fraction; MI, myocardial infarction; and EP, electrophysiological study.

#### Methods

Screening and Registry enrollment was a 2-step process. A 1-page screening form was completed for all patients seen or referred to an AVID center who had experienced VF or VT, regardless of cause. In addition, patients who experienced unexplained out-of-hospital syncope and were found to have structural heart disease and symptomatic VT induced at electrophysiological study were screened. Most local Investigational Review Boards allowed verbal patient consent for the Registry (because no active patient participation or risk was involved), but a minority required written consent.

Screening classified the index arrhythmia to determine eligibility for the randomized trial (categories A, B, and C, Figure 1). Screening also excluded certain patients from the registry (Figure 2).

Generally, only patients with a reasonable likelihood of being eligible to receive antiarrhythmic drug therapy, ICD therapy, or both were included in the AVID Registry. However, patients who experienced out-of-hospital VT or VF thought to be of transient or correctable cause (eg, in conjunction with myocardial infarction, acute ischemia, drug overdose, or severe electrolyte imbalance) were included to evaluate whether their outcome was better than that of the patients with other arrhythmias, as traditionally believed.2

The second step was to complete the AVID Registry form (Appendix 1) for any patient without Registry exclusion. Demographics, baseline data, and trial eligibility (pages 1 and 2) were obtained during screening (trial exclusion criteria are listed under

#### **Exclusion Checklist AVID Registry**

#### Registry Exclusion Checklist:

Screen patient for all readily available information. Exclusions are not prioritized. Check yes for EACH exclusion noted in the chart.

Ye	s NC	)	
O	O	(1)	Event occurred in-hospital within 5 days after myocardial infarction
O	O	(2)	Event occurred within 5 days after cardiac surgery or PTCA
O	O	(3)	Prior ICD implant or attempted implant
О	О	(4)	Intra-aortic balloon pump or other device or inotropic drug (not digitalis) necessary for hemodynamic support
O	O	(5)	NYHA Class IV heart failure
O	O	(6)	Currently on a heart transplant waiting list
O	O	(7)	Life expectancy <1 year
O	O	(8)	Chronic serious bacterial infection
O	O	(9)	Inability to give verbal assent due to severe neurologic impairment
O	О	(10)	Died during screening

Figure 2. Checklist of exclusions from Registry.

# **AVID** Enrollment

```
Screened
  5.989
Registered
                                                              Registered
  (all sites)
                                                         (NDI participants only)
  4,595
                                                                  4,451
                         Excluded for:
                                                          - 32.4%
          32.2% - Lower risk (noneligible) arrhythmia
          12.9% - Medical exclusions
                                                          - 12.8%
                                                          - 1.0%
           1.0% - Exposure to amiodarone
                                                            4.7%
           4.6% - Compliance exclusions
                                                          - 7.5%
           7.7% - Treatment already determined
          18.5% - Patient/physician refusal
                                                          - 18.3%
           1.0% - Other reason
                                                            1.0%
Randomized
                                                             Randomized
                                                             996 (22.4%)
1.016 (22.1%)
```

Figure 3. AVID enrollment: Number of patients screened, registered, randomized, and followed up by NDIS.

item 8). Page 3 was completed at hospital discharge and covered procedures done after the index arrhythmia, discharge medications, heart rate, blood pressure, creatine kinase MB isoenzyme measurements obtained within 3 days after the index arrhythmia, the date of the index arrhythmia, and the admitting and discharge dates for the screening hospitalization. These 3 pages were sent to the Data Coordinating Center.

The fourth page was used solely for obtaining follow-up information through the National Death Index Service (NDIS).<sup>23</sup> Only page 4 related the Registry identification number to specific patientidentifying information, such as name and social security number. To ensure patient confidentiality, page 4 was kept at the local site and the data were not stored at the coordinating center.

Follow-up of the Registry patients was through the NDIS. Each AVID center entered page 4 data on a diskette; these were sent to the NDIS, which conducted a search based on name, social security number, and birth date for matches against routinely assembled vital statistics (ie, mortality). Using the Registry identification number as a link, the results of this search were incorporated into the Registry database. There were 144 registrants (3.1%) without patient identifiers, either because the site did not participate in the Registry follow-up (n=128) or one of the key identifiers was missing (n=16).

This article reports results based on vital status reports through December 31, 1996, and thus is restricted to the 4219 registry patients with patient identifiers whose index arrhythmic event occurred before January 1, 1997. The NDIS search missed 3 of the 162 deaths (1.85%) that occurred in trial patients.

Survival estimates are based on the methods of Kaplan and Meier.<sup>24</sup> Comparisons among survival curves were made by the global log-rank test.<sup>25</sup> No differences were noted between analyses of all sites and analyses restricted to centers with relatively large numbers of registrants; thus, analyses presented are of all enrolling centers and all Registry patients.

# Results

#### **Study Population**

Of 5989 patients screened, 4595 (77%) were registered, of whom 1016 (22%) were randomized. Of the 4595 registered,

TABLE 1. Reasons for Nonrandomization

Patient/family refusal	45.1%
Treatment predetermined by referring physician	28.2%
Physician refusal	11.5%
Previous amiodarone use	1.9%
Other	13.4%

Includes 1509 patients with trial-eligible arrhythmia and no medical exclusion.

TABLE 2. Eligible Patients: Discharge Therapies

	Randomized, % (n=1016)	Nonrandomized, % (n=1509)
AAD, no ICD	49.6	39.0
ICD, no AAD	45.3	38.9
AAD and ICD	3.9	10.8
Neither AAD or ICD	1.3	11.2
	P<	<0.001

AAD indicates antiarrhythmic drug.

4451 provided identifiers enabling NDIS follow-up; of these, 996 were randomized. Reasons for exclusion from the trial are shown in Figure 3.

# **Registry Demographics and Representativeness of Trial Patients**

The 4595 registrants averaged 64 years of age, and 77% were male. The mean left ventricular ejection fraction was 35%, and 77% had evidence of coronary artery disease (CAD). Of the 3579 nonrandomized patients, 1509 were AVID trialeligible (trial-eligible arrhythmia and no medical exclusions) and 2070 were noneligible.

## **AVID Trial-Eligible Patients**

#### Reasons for Nonrandomization

The reasons for not randomizing eligible patients are given in Table 1. In these qualifying patients, patient or family refusal, followed by physician preference, were the most frequent causes for nonrandomization.

## Clinical Characteristics

Among trial-eligible patients, only a few statistically significant differences between those randomized and those not

randomized were found. Randomized patients were slightly older (65.1 versus 63.4 years); more frequently were male (79.4% versus 74.5%); more frequently had CAD (81.5% versus 75.7%) or a past history of myocardial infarction (67.0% versus 58.3%), congestive heart failure (CHF) (46.8% versus 41.8%), syncope (13.1% versus 9.5%), hypertension (55.8% versus 47.9%), or diabetes (24.3% versus 20.6%); and less frequently had no evident structural disease (2.9% versus 5.2%). However, the magnitude of the differences was small (<15% proportionate or <5% absolute differences) and unlikely to have a significant impact on enrollment or treatment decisions.

Cardiac procedures before or after the index arrhythmia were similarly distributed by randomization status in eligible patients. Overall, 28% had previously undergone bypass surgery, and 9% had had a percutaneous coronary intervention without differences between groups. After the arrhythmic event, 7.4% underwent bypass surgery and 3.2% a percutaneous coronary intervention. Nonrandomized patients rarely underwent ablation procedures (2%).

#### Discharge Cardiac Therapies

Discharge cardiac (nonarrhythmic) therapies were similarly distributed in eligible patients in both groups, with 27% of patients prescribed  $\beta$ -blockers, 14% calcium antagonists, 34% nitrates, 50% diuretics, and 24% warfarin. Two exceptions were small differences in ACE inhibitor use (68.5% versus 57.6%, randomized versus nonrandomized) and aspirin use (59.1% versus 54.0%).

In each group of eligible patients, ICD and antiarrhythmic drug therapies were used with equal frequency at discharge, with each being used in  $\approx$ 50% of patients (Table 2). By study design, both combination therapy (4%) and neither therapy

TABLE 3. Clinical Characteristics of Registrants by Presenting Arrhythmia

	VF	VT With Syncope	Symptomatic VT	Asymptomatic VT	VT/VF of Transient/Correctable Cause	Unexplained Syncope, VT Inducible
No.	1399	598	1065	497	270	390
Age, y	62.8	65.8	64.6	63.3	61.2	65.0
EF	36.2	32.7	31.8	36.6	41.4	33.7
Male, %	71.1	77.1	80.3	79.3	72.2	82.8
CAD, %	72.6	74.6	82.3	73.8	81.5	81.3
CM, %	19.0	17.2	15.2	13.3	8.9	17.9
No identified cardiac disease, %	6.1	5.9	4.4	9.9	7.0	0.8
History, %						
VF	7.0	2.5	3.7	4.2	3.0	0.0
VT	7.5	21.1	26.5	35.0	10.0	0.0
AF	25.0	28.3	22.9	21.5	19.3	20.0
MI	48.7	60.2	69.3	62.8	45.2	67.4
CHF	42.0	44.1	42.3	31.4	22.2	35.9
Diabetes	21.4	24.0	19.3	18.5	15.9	20.8
CABG/PTCA	29.6	30.3	36.9	34.8	24.4	41.0
Other cardiac procedures	15.0	14.5	16.5	16.3	6.3	14.1
On AAD at index event, %	10.6	16.9	19.2	28.8	14.1	11.0

EF indicates left ventricular ejection fraction; CM, cardiomyopathy; AF, atrial fibrillation; MI, myocardial infarction; and AAD, antiarrhythmic drug.

TABLE 4. Postevent Procedures and Discharge Therapies of Registrants by Presenting Arrhythmia

	VF	VT With Syncope	Symptomatic VT	Asymptomatic VT	VT/VF of Transient/Correctable Cause	Unexplained Syncope, VT Inducible
CABG/PTCA	16.9	12.2	9.7	8.0	41.5	6.2
Ablation	1.1	3.0	3.8	16.5	2.2	1.8
Pacemaker	4.1	4.7	4.0	3.6	3.7	5.9
$\beta$ -Blocker	29.6	24.0	24.9	22.5	44.2	22.8
Calcium channel blocker	15.7	12.6	12.9	12.6	19.4	20.8
Digitalis	41.3	42.5	39.2	31.2	28.7	39.5
ACE inhibitor	57.7	57.0	59.6	49.3	39.9	59.2
Nitrates	29.6	28.9	35.0	26.4	37.7	29.0
Diuretics	46.7	51.4	47.7	38.7	33.5	46.2
Warfarin	24.5	24.4	26.4	17.2	19.7	23.6
Aspirin	52.9	55.3	57.7	58.2	66.3	57.4
AAD, no ICD	34.9	47.6	43.7	51.3	26.3	31.5
ICD, no AAD	44.5	32.8	33.8	18.0	16.7	46.2
AAD and ICD	8.7	9.7	13.1	9.1	3.7	11.5
Neither AAD nor ICD	11.9	9.9	9.5	21.6	53.3	10.8

AAD indicates antiarrhythmic drug. Values are %.

(1%) were to be avoided in randomized patients, whereas nonrandomized patients could receive both therapies (11%) or neither therapy (11%).

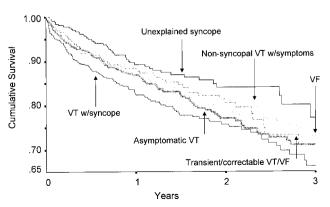
### Registry Patients Followed Up by the 1996 NDIS

A total of 4219 patients qualified for and were entered into the Registry by December 31, 1996, and were followed for vital status through December 31, 1996 (via the NDIS). The following is based on these 4219 patients.

## Clinical Characteristics

Table 3 presents the main clinical characteristics of the Registry patients (including trial patients) grouped according to presenting arrhythmia. Mean ages ranged from 61 to 66 years. The prevalence of CAD ranged from 73% to 82%. The range of mean ejection fractions was 32% to 41%. There was a 2-fold difference in history of CHF (22% to 44%), but a history of diabetes was present in ≈20% of all groups.

# Survival by Arrhythmia Type



**Figure 4.** Survival function curves for AVID registry arrhythmia groups (*P*=0.007 for comparison among curves, global log-rank).

Table 4 shows the postevent index arrhythmia procedures and discharge therapies in the patients grouped by presenting arrhythmia. Coronary bypass surgery was performed in 42% of the transient VF/VT group, 17% of the VF group, and  $\approx 10\%$  in other groups. There were substantial differences in rates of arrhythmia ablation procedures (1% to 16%) and use of  $\beta$ -blockers (23% to 44%), digitalis (29% to 43%), ACE inhibitors (40% to 60%), and diuretics (34% to 51%). The rate of ICD implantation varied from 20% to 58% and the use of antiarrhythmic drugs from 30% to 60%.

#### Survival

A relatively high rate of mortality was noted for all 6 arrhythmia groupings, with 2-year survival rates ranging from 76% in patients presenting with syncopal VT to 84% in patients with unexplained syncope and inducible VT (Figure 4) (P=0.007 among groups).

Survival was similar across arrhythmia groups for patients without severe ventricular dysfunction (2-year rates ranged from 82% to 86%, P=NS) but was more variable for patients with poor ejection fraction (<0.35), with 2-year rates ranging from 68% to 83% (P=0.021) (Table 5).

## **Discussion**

# Summary of the AVID Registry Experience

The AVID Registry provides unique, prospectively collected information on a large and broadly representative population of patients surviving life-threatening ventricular tachyarrhythmias. In this article, we present in detail the design of the Registry. We confirm the preliminary observations of Kim et al<sup>22</sup> as to the representativeness of the trial patients. Interestingly, the use of antiarrhythmic drug and ICD therapies was almost equal in the nonrandomized patients. We also present baseline and postevent character-

	n*	EF≥0.35, %	n*	EF<0.35, %	n	All, %
VF	656	85.7	680	73.6	1399	79.7
VT with syncope	241	81.5	339	73.0	598	75.7
Nonsyncopal VT with symptoms	419	84.7	624	78.6	1065	81.3
Asymptomatic VT	235	85.3	217	67.7	497	77.2
Transient/correctable VT/VF	167	86.1	88	70.8	270	80.6
Unexplained syncope	158	84.8	209	82.7	390	84.1

TABLE 5. Two-Year Survival Rates by Arrhythmia Type and EF

istics of the Registry patients subgrouped by presenting arrhythmia, as well as outcome data.

The AVID Registry constitutes the largest published cohort of patients with life-threatening ventricular arrhythmias of which we are aware.<sup>26</sup> It consists of patients who were eligible for the AVID main trial and were randomized, those not randomized but qualifying for AVID, and those not randomized and not qualifying. Reasons for and frequency of not randomizing patients were recorded; nonrandomization most often was due to patient or family refusal, followed by physician preference. Interestingly, patient/physician preference (or bias) for drug and device treatments was virtually identical. A strong preference for an ICD over antiarrhythmic drug therapy (or vice versa) was not observed in this Registry population, suggesting the presence of little overall therapeutic selection bias in participating AVID centers.

## Generalizability

The issue of generalizability of AVID's efficacy results to the universe of patients with VT/VF is of prime importance. The knowledge that AVID results were generated from a large percentage of eligible patients (41%) and that nonrandomized but eligible patients were strikingly similar also suggests that results of the study may be applied with more confidence to AVID trial—eligible patients seen in clinical practice. In contrast, many other studies have enrolled a small percentage of patients or have failed to keep a Registry, so that the patient pool's "denominator" is unknown and uncharacterized. 17 Furthermore, several other VT/VF types previously thought to be low-risk were found to be at a risk similar to that of the AVID trial-eligible patients. The surprisingly high and similar mortality rates across the arrhythmia subgroups are being investigated extensively, including ongoing collection of additional baseline and follow-up data. Preliminary multivariate analyses did not explain the similarity of the high rates on the basis of wellknown baseline risk predictors, such as ejection fraction (Table 5) or the choice of antiarrhythmic therapy. The factors influencing treatment selection in these nonrandomized groups are unknown, but given the approximately equal use of ICD and antiarrhythmic drug therapy, as in the AVID main trial, this finding raises the possibility that the expense of an ICD may be justified by a potentially large but as yet unproven treatment benefit in additional groups of patients, especially when associated with a low ejection fraction (<0.35).

The lower and similar mortality observed for patients with left ventricular ejection fraction  $\geq$ 0.35 raises the question, at

least from a cost-effectiveness perspective, of the suitability of ICD implantation in patients with relatively preserved left ventricular function.

#### Transient/Correctable Cause of VT/VF

The high mortality rate for patients with VT/VF thought to be provoked by reversible factors deserves special comment: 42% of patients had in-hospital revascularization, 2% ablation, and 4% pacemakers; many others had adjustment in medical therapy (eg, potassium replacement). However, fewer than half (47%) were discharged on specific antiarrhythmic therapy. Their poor subsequent outcome (29% mortality at 3 years) suggests that clinical judgment regarding reversibility and recurrence risk is not very accurate and that more aggressive and specific antiarrhythmic therapy (including ICD) may be appropriate for many of these patients, especially if they have a low ejection fraction (<0.35).

## **Registry Caveats and Recommendations**

Although the Registry form collected a substantial amount of information, several subsequently proposed analyses would have required that some data items be modified. These included details with regard to primary versus secondary health insurer admission; discharge dates of the first hospitalization related to the index arrhythmia, in addition to the admission and discharge dates for the screening hospitalization; and finally, performance and results of electrophysiological studies (including drug testing).

Although our process for follow-up through the NDIS may appear cumbersome, we found that it worked well. Total mortality (and death certificate codes) but not cause-specific mortality (ie, sudden death versus other causes) is available. Finally, characteristics of patients at sites that enrolled high and low numbers of patients were similar.

In conclusion, the AVID Registry design formed an important part of the AVID study program and has provided important information about the natural history of VT/VF, current practice patterns across a broad base of institutions, and a firm basis for generalizing the AVID study results to the general population of patients with AVID-type ventricular arrhythmias.

# Appendix 1

## Four-Page Registry Case Report Form

The AVID Registry case report form is shown in Figure 5.

<sup>\*</sup>Ejection fraction (EF) was missing for 4.4% of patients.

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	Complete items 11 - 15 after evaluation and initial treatment for index arrhythmia.				
<b>AVID Registry</b> <sup>Fox 10:</sup> (205) 685-7569 or (800) 253-6404	11 Cardiac procedures since index arrhythmia:				
1 Date of index arrhythmia: Registry ID	O None O Aneurysm/endocardial resection O Pacemaker implant				
Month Day Year	O CABG O Valve repair/replacement O NTL ICD Implant O PTCA/atherectomy O Thrombolyfic therapy O Epicardial ICD Implant				
2 Location of index arrhythmia: O Out-of-hospital O ER O In-Hospital	O Ablation				
Reason for Admission: Monitored prior Post invasive procedure	O Other:				
O Cardiac O Yes O Yes	12 Discharge medications or current medications (if not currently hospitalized):				
0.0	Yes No Yes No O O Amiodarone O O ACE inhibitor				
3 Demographics:  Gender: Birth date: / / /	O Sotalol     O Other vasodilator or afterload reducing agent				
O Male O Female Month Day Year	O Other antiarrhythmic O O Nitrate O O Beta blocker (not sotalol) O O Diuretic				
	O O Calcium channel blocker O O Warfarin O O Digitalis O O Aspirin or antiplatelet				
O White O Black O Asian	5 - The state of t				
O Native American O Other	13 Physical exam (current or last exam prior to hospital discharge):				
☐ Medicare/Medicaid ☐ None	Sitting Heart Rate: bpm				
	Sitting Blood Pressure (systolic/dlastolic): / mmHg				
4 Antiarrhythmic therapy:	14 Were enzymes collected? > 0 Yes 0 No				
Was patient taking antiarrhythmic drug(s) at the time of the index arrhythmia?  ○ Yes ○ No	14 Were enzymes collected? > O Yes O No If yes, record peak measurements obtained within 3 days after index arrhythmia				
Did patient receive amiodarone in the six months prior to screening (before or after event)?	Peak CPK IU/L				
O Yes O No	Hours post index arrhythmia (CPK) 0 0-6 0 >6-12 0 >12-24 0 >24-48 0 >48-72 0 Unik				
5 Clinical history (prior to index arrhythmia):  Yes No Yes No Yes No	Peak MB %, or ng/ml O Unknown O Not Done				
O O Prior VF O O Prior VT O O A F/flutter	15 Screening hospitalization (i.e., admission when screened for AVID):				
O OMI O OCHF O O Bradycardia or AV block	Date of hospital admission (this visit): Date of hospital discharge or death:				
O O Hypertension O O Diabetes requiring treatment					
O O Neoplasm O O Unexplained syncope O O Present smoker	Month Day Year Month Day Year				
O O Hyperlipidemia O O Use of class I or III antiarrhythmic drugs	Vital status at discharge: O Alive O Dead				
6 Organic cardiac disease: (Check all applicable)	16 Name and social security number:				
O CAD O CAD	to Name and social security number:				
O Hypertrophic cardiomyopathy					
Non-ischemic dilated cardiomyopathy	Last Name				
O Valvular					
O Other:	First Name MI				
O No identifiable heart disease	Social Security Number:				
7 Cardiac procedures prior to index arrhythmia: (Check all applicable)					
O None O Aneurysm/endocardial resection O Pacemaker Implant					
O CABG O Valve repair/replacement O Ablation	Birth date: (from page 1)				
O PTCA/atherectomy O Thrombolyflic therapy O Other:					
	Month Day Year				
Main trial exclusion checklist: (Check all applicable)     Screen patient for all readily available information. Exclusions are not prioritized.	Month Day Year				
Cardiac: Yes No					
(1) CABG or PTCA planned or performed since index event and EF > 0.40     (2) Arrhythmia surgery or procedure planned or successfully completed	Do not fax this page. Complete and store for future reference.				
O (3) Index event occurred on arrivodarone O (4) Exposure to amiodarone in last 6 mo., unless total dose < 10 g or exposure < 2 weeks					
or serum level is < 0.2 mcg/ml  (5) Other contraindication to amlodarone					
O (6) Long QT syndrome (e.g., QTc of > 500 msec, recurrent syncope, and/or ventricular arrhy O (7) AF or other supraventricular arrhythmia requiring class I or III antiarrhythmics	di d				
(8) Symptomatic sinus bradycardia, 2° or 3° AV block in the absence of a pacemaker     (9) Arthythmia treatment already determined by private physician					
O (10) Excessive arrhythmia making crossover likely					
Non-Cardiae: Yes No					
O (11) Condition likely to limit cooperation     O (12) Geographically inaccessible					
O (13) Current conflicting study O (14) Prisoner or ward of the state					
9 Trial eligibility: Is this patient eligible for trial inclusion?  O Yes O No -> Go to item 10	Flower F AVID D				
> Was patient randomized?	Figure 5. AVID Registry case report form.				
O Yes -> Affix ID label here:					
No Why Not?(check all applicable)     Died before randomization					
O Patlent/family refusal O Physician refusal					
O Other:					
10 LVEF: (Quantification of EF is required for randomized patients)					
or (Registry only): O Normal O Moderately abnormal					
O Mildly abnormal O Severely abnormal					
Date obtained:  Method: O Radionuclide ventriculogram					
O Contrast anglography O MRI/CT					

# Appendix 2

## **AVID Investigators**

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