ORIGINAL ARTICLE

Home Use of Automated External Defibrillators for Sudden Cardiac Arrest

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ABSTRACT

BACKGROUND

The most common location of out-of-hospital sudden cardiac arrest is the home, a situation in which emergency medical services are challenged to provide timely care. Consequently, home use of an automated external defibrillator (AED) might offer an opportunity to improve survival for patients at risk.

METHODS

We randomly assigned 7001 patients with previous anterior-wall myocardial infarction who were not candidates for an implantable cardioverter–defibrillator to receive one of two responses to sudden cardiac arrest occurring at home: either the control response (calling emergency medical services and performing cardiopulmonary resuscitation [CPR]) or the use of an AED, followed by calling emergency medical services and performing CPR. The primary outcome was death from any cause.

RESULTS

The median age of the patients was 62 years; 17% were women. The median followup was 37.3 months. Overall, 450 patients died: 228 of 3506 patients (6.5%) in the control group and 222 of 3495 patients (6.4%) in the AED group (hazard ratio, 0.97; 95% confidence interval, 0.81 to 1.17; P=0.77). Mortality did not differ significantly in major prespecified subgroups. Only 160 deaths (35.6%) were considered to be from sudden cardiac arrest from tachyarrhythmia. Of these deaths, 117 occurred at home; 58 at-home events were witnessed. AEDs were used in 32 patients. Of these patients, 14 received an appropriate shock, and 4 survived to hospital discharge. There were no documented inappropriate shocks.

CONCLUSIONS

For survivors of anterior-wall myocardial infarction who were not candidates for implantation of a cardioverter–defibrillator, access to a home AED did not significantly improve overall survival, as compared with reliance on conventional resuscitation methods. (ClinicalTrials.gov number, NCT00047411.)

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UDDEN CARDIAC ARREST REMAINS AN unsolved public health problem, with approximately 166,200 out-of-hospital cardiac arrests occurring annually in the United States.1 The use of automated external defibrillators (AEDs) by trained lay responders in community-based public-access defibrillation programs has been shown to increase survival after sudden cardiac arrest. However, what effect the use of the device has on overall mortality for the community at risk is unknown.²⁻⁵ Particularly impressive results have been reported when sudden cardiac arrest is witnessed and an AED is immediately available, as on airplanes and in casinos and airports.6-8 However, the effect of such programs is limited, since about three quarters of sudden cardiac arrests occur in the home,9,10 where successful resuscitation is typically achieved in only 2% of cases.11

The combination of ease of use, low cost, and negligible maintenance makes home AED therapy a potentially attractive approach to a major public health problem. The purpose of the Home Automated External Defibrillator Trial (HAT) was to test whether an AED in the home of patients at intermediate risk of sudden cardiac arrest could improve survival.

METHODS

STUDY DESIGN

Our international, multicenter clinical trial was sponsored by the National Heart, Lung, and Blood Institute (NHLBI).¹² AEDs were provided free of charge by Philips Medical Systems and Laerdal Medical as a subsidiary distributor. Both companies also provided funding for research meetings. The corporate sponsors had no role in the design of the trial, the collection or analysis of the data, the writing of the manuscript, or the decision to publish the results. The trial was approved by the institutional review board at each participating center and was performed with the oversight of an NHLBI-appointed data and safety monitoring board.

PATIENTS

Patients whose medical condition was stable and who had had a previous anterior-wall Q-wave or non–Q-wave myocardial infarction were selected for enrollment because such patients represent a sizable group known to be at increased risk for sudden cardiac arrest.¹³⁻¹⁵ Patients were excluded from the study if they were candidates for implantable cardioverter-defibrillator therapy, according to published guidelines.¹⁶⁻¹⁹ Contemporary evidence-based drug therapy after myocardial infarction was encouraged for all patients. Patients were required to have a spouse or companion who was willing and able to call for assistance from emergency medical services, perform cardiopulmonary resuscitation (CPR), and use an AED. Patients with an implantable cardioverterdefibrillator, with their own AED, or with a do-notresuscitate order were excluded. Written informed consent was provided by all patients and their spouses or companions.

GROUP ASSIGNMENTS

Patients who had received conventional training to respond to a cardiac arrest were randomly assigned in equal proportions to receive either an AED for home use or no AED. Randomization was performed with the use of permuted blocks, stratified according to clinical center.

The goal for the control group after sudden cardiac arrest was an immediate telephone request for assistance from emergency medical services and prompt initiation of CPR, in accordance with published guidelines for basic life support.²⁰ Patients and their spouses or companions in the control group received a video, specifically scripted to educate laypersons on how to call for assistance and perform CPR.²¹

The goal in the AED group was to use the AED first, in accordance with published guidelines for AED use.²² The AED that was selected for this trial, the Home HeartStart (Philips), is the only device that is approved by the Food and Drug Administration for home use. Spouses or companions were instructed to call emergency medical services and perform CPR, as in the control group. However, in the AED group, spouses or companions placed the call for assistance and performed CPR after the application of the AED. If two or more rescuers were present, the call to emergency medical services was to occur simultaneously with the use of the AED. Patients in the AED group received a video that was specifically scripted to educate laypersons on how to use the AED, call for assistance, and perform CPR.²¹ Patients and their spouses or companions were advised to keep the AED in a prominent location in the home to facilitate ease of access and regular visual confirmation of the AED's readiness.

TRAINING AND FOLLOW-UP

In both study groups, video-based training was used to standardize instruction and facilitate refresher training at intervals of 3 months. Investigators were also encouraged to offer hands-on training at enrollment and during annual followup visits. A telephone call between annual visits was used to obtain information on vital status and encourage viewing of the video.

DEFINITION AND ADJUDICATION OF OUTCOMES

The primary outcome was death from any cause. Secondary outcomes included death from sudden cardiac arrest, survival from witnessed sudden cardiac arrest in the home, and the outcome after the use of an AED.

All deaths and sudden cardiac arrests were adjudicated with the use of prespecified criteria by a clinical events committee whose members were unaware of study-group assignments. Death was classified as being due to cardiac causes or noncardiac causes according to the most proximate cause. Cardiac arrest was defined as a sudden loss of consciousness requiring CPR or transthoracic defibrillation. Death and cardiac arrest were classified as sudden if they occurred within 1 hour after the onset of major accelerating symptoms; cardiac arrest was classified as witnessed if the patient was seen or heard within 5 minutes before collapse. Resuscitated cardiac arrest was defined as survival for more than 48 hours. In the event of use of an AED, the electrocardiographic data were retrieved whenever possible, and rhythms were categorized as ventricular fibrillation, asystole, or organized rhythm.23,24

STATISTICAL ANALYSIS

The trial was designed to have a power of 90% to detect a 20% reduction in the relative risk of death from any cause, with a target recruitment of 7000 patients during a 2.5-year period and a minimum follow-up of 2 years.¹² We assumed an annual rate of death of 4% in the control group, a crossover rate of less than 2%, and a loss of partner or companion of less than 5%. The anticipated reduction in mortality was based on the assumption that half the number of deaths would be due to sudden cardiac arrest and that the use of an AED would reduce the rate of death from sudden cardiac arrest by 40%, with the expectation that patients would be at home and in the presence of their partners or companions more than 50% of the time.

We performed all major study-group comparisons according to the intention-to-treat principle. All statistical tests were two-tailed. Cumulative event rates were calculated with the use of the Kaplan-Meier method.²⁵ Event times for all patients were measured from the time of randomization. A log-rank test was used for the comparison of the AED group with the control group with respect to the primary outcome.²⁶ Hazard ratios with associated confidence intervals were derived with the use of a Cox proportional-hazards model.27 The Cox model was also used to assess the consistency of the treatment effect by testing for interactions between treatment and prespecified baseline characteristics. The log-rank test and Cox model were also used in the assessment of study-group differences and analyses for secondary outcomes.

Five interim analyses of the data were performed and reviewed by the data and safety monitoring board. Interim comparisons between study groups used two-sided, symmetric O'Brien– Fleming boundaries that were generated with the alpha-spending-function approach to groupsequential testing.^{28,29}

RESULTS

STUDY POPULATION

From January 23, 2003, to October 20, 2005, a total of 7001 patients underwent randomization at 178 clinical sites in seven countries; 3506 patients were assigned to the control group, and 3495 were assigned to the AED group. The patients were enrolled at centers in the United States (29.1%), Canada (27.0%), Australia (20.9%), the United Kingdom (14.6%), New Zealand (8.1%), the Netherlands (0.1%), and Germany (0.1%).

The median age of the patients was 62 years; 17.4% were women, and 12.9% were members of a racial or ethnic minority group (Table 1). At baseline, all patients had an anterior-wall myocardial infarction; 64.4% had a Q-wave event, and 35.6% had a non–Q-wave event. The median interval between the date of the qualifying myocardial infarction and trial enrollment was 1.7 years.

The designated rescuers were younger than the patients (median age, 58 years) and predominantly female (82.5%); most were married to the patient (87.8%) (Table 1). In 33.3% of households, there were two or more potential rescuers. A total of 42.6% of the patients and 48.8% of the spouses

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Characteristic	Control Group (N=3506)	AED Group (N=3495)
Patients		
Age — yr		
Median	62.0	62.0
Interquartile range	54.0–70.0	54.0–70.0
Female sex — no. (%)	626 (17.9)	594 (17.0)
Racial or ethnic minority — no. (%)†	478 (13.6)	428 (12.2)
Time since most recent anterior myocardial infarction — no. (%) \ddagger		
≤l Mo	290 (9.7)	272 (9.2)
>1 Mo to 3 mo	284 (9.5)	300 (10.1)
>3 Mo to 6 mo	284 (9.5)	261 (8.8)
>6 Mo to 1 yr	331 (11.1)	354 (11.9)
>l Yr	1798 (60.2)	1780 (60.0)
Employment status — no. (%)		
Full-time	1123 (32.0)	1161 (33.2)
Part-time	329 (9.4)	368 (10.5)
Not employed	2054 (58.6)	1966 (56.3)
Estimated daily time alone at home — hr		
Median	1.5	1.5
Interquartile range	0.5–4.0	0.5-4.0
Estimated daily time away from home — hr		
Median	4.0	4.0
Interquartile range	2.0-8.0	2.0-8.0
Previous procedures — no. (%)		
Percutaneous coronary revascularization	1890 (53.9)	1852 (53.0)
Coronary-artery bypass grafting	907 (25.9)	960 (27.5)
Coexisting conditions — no. (%)		
Hypertension	1931 (55.1)	1838 (52.6)
Diabetes	792 (22.6)	712 (20.4)
Hypercholesterolemia	2804 (80.0)	2753 (78.8)
Stroke	217 (6.2)	220 (6.3)
Measured ejection fraction — no. (%)	2803 (79.9)	2821 (80.7)
Left ventricular ejection fraction — %		
Median	45.0	45.0
Interquartile range	35.0-55.0	35.0-55.0
Atrial fibrillation or flutter — no. (%)	361 (10.3)	377 (10.8)
Systolic blood pressure — mm Hg		
Median	124.0	124.0
Interquartile range	112.0–136.0	112.0–136.0
Diastolic blood pressure — mm Hg		
Median	73.0	73.0
Interquartile range	66.0-80.0	68.0-80.0
Heart rate — beats/min		
Median	65.0	65.0
Interquartile range	60.0–72.0	60.0–72.0

Characteristic	Control Group (N=3506)	AED Group (N=3495)
Patients	(()
Body-mass index		
Median	27.8	27.7
Interquartile range	25.1-30.9	24.9-30.9
NYHA class — no. (%)		
	2307 (65.8)	2263 (64.7)
11	1016 (29.0)	1037 (29.7)
III	174 (5.0)	193 (5.5)
IV	9 (0.3)	2 (<0.1)
Left ventricular hypertrophy — no. (%)§	165 (4.7)	166 (4.8)
Duration of QRS interval — msec		
Median	91.0	92.0
Interquartile range	80.0–100.0	80.0-100.0
Type of myocardial infarction — no. (%)		
Anterior Q-wave	2237 (63.8)	2272 (65.0
Anterior non-Q-wave	1269 (36.2)	1222 (35.0
Use of medication — no. (%)		(
Beta-blocker (other than sotalol or amiodarone)	2793 (79.7)	2738 (78.3
ACE inhibitor or angiotensin-receptor blocker	2853 (81.4)	2866 (82.0
Statin	3141 (89.6)	3100 (88.7
Daily use of aspirin	3047 (86.9)	3016 (86.3
Digoxin	240 (6.8)	249 (7.1)
Warfarin	600 (17.1)	649 (18.6
Any antiarrhythmic drug	138 (3.9)	160 (4.6)
Spouse or companion		
Relationship to patient — no. (%)		
Spouse	3055 (87.1)	3095 (88.6
Companion	451 (12.9)	400 (11.4
Age — yr		
Median	58.0	58.0
Interquartile range	49.0–67.0	50.0–66.0
Employment status — no. (%)		
Full-time	1110 (31.7)	1113 (31.8)
Part-time	619 (17.7)	577 (16.5
Not employed	1777 (50.7)	1805 (51.6
Estimated daily time away from home — hr	. ,	
Median	4.0	4.0
Interquartile range	2.0–7.5	2.0-8.0
Completed secondary school — no. (%)	2851 (81.3)	2831 (81.0)

* ACE denotes angiotensin-converting enzyme, AED automated external defibrillator, and NYHA New York Heart

Association. The body-mass index is the weight in kilograms divided by the square of the height in meters.

† Race or ethnic group was self-reported.

Percentages are based on 2987 patients in the control group and 2967 in the AED group.
 Percentages are based on 3485 patients in the control group and 3477 in the AED group.

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or companions worked either full-time or parttime. The median estimated time that patients were alone at home was 1.5 hours per day; other persons at home with the patient may or may not have included the study rescuer. The patients reported a median estimated time away from home of 4.0 hours.

Patients were followed through September 30, 2007. The median duration of follow-up was 37.3 months (range, 20.4 to 55.6). Data regarding vital status, current to within 3 months before study closure, were obtained for 100% of the patients who underwent randomization.

COMPLIANCE AND CROSSOVERS

In the AED group, 167 patients (4.8%) had a spouse or companion who was unable or unwilling to use the AED during follow-up. The corresponding number in the control group was 132 of 3272 patients (4.0%) for whom follow-up data were available. Crossover to therapy with an implantable cardioverter–defibrillator during follow-up occurred in 145 of 3435 patients in the AED group (4.2%) and in 155 of 3371 patients in the control group (4.6%).

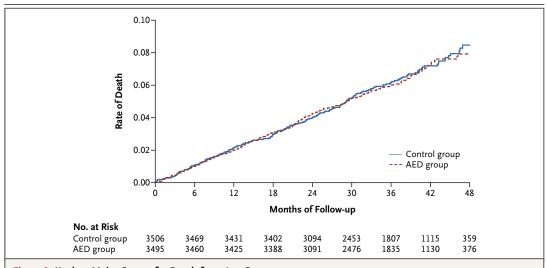
PRIMARY OUTCOME

A total of 450 patients died. Of these patients, 228 (6.5%) were in the control group, and 222

(6.4%) were in the AED group. As compared with the control group, the AED group had a similar risk of death (hazard ratio, 0.97; 95% confidence interval, 0.81 to 1.17; P=0.77). The mean annual mortality during 4 years of follow-up was 2.1% in the control group and 2.0% in the AED group (Fig. 1). The primary outcome did not differ among the major prespecified subgroups according to the following factors: age (≥ 65 years vs. <65 years), sex, Q-wave versus non-Q-wave myocardial infarction, and nationality (United States vs. all other countries) (Fig. 2). Treatment comparisons within subgroups were consistent with the overall study results, although the difference in treatment effect in patients with diabetes, as compared with those without diabetes, was statistically significant (P=0.04).

CAUSE, MODE, AND CIRCUMSTANCE OF DEATH

The adjudicated cause and mode of death in each of the study groups are shown in Table 2. Only 169 of the 450 deaths (37.6%) were deemed to be caused by tachyarrhythmia (i.e., consistent with ventricular fibrillation or ventricular tachycardia). Death was attributed to heart failure or nonarrhythmic cardiac causes in 96 patients (21.3% of deaths) and to noncardiac causes in 170 patients (37.8%). Thirteen deaths (2.9%) could not be classified because of insufficient data. There were





Among 7001 patients who had previously survived anterior-wall myocardial infarction, there were 228 deaths in the control group (which was trained in calling emergency medical services and performing cardiopulmonary resuscitation [CPR]) and 222 deaths in the group that was instructed in the home use of an automatic external defibrillator (AED), followed by calling emergency medical services and performing CPR (hazard ratio for the AED group, 0.97; 95% confidence interval, 0.81 to 1.17; P=0.77). Vital status was known for 100% of patients within 3 months before the end of the trial.

no differences between the control group and the AED group in the adjudicated mechanisms of death for any category.

Of the 169 deaths from cardiac tachyarrhythmia, 160 were from sudden cardiac arrest. The initial place of collapse was the home for 117

patients, a public place for 9 patients, a hospital or long-term care facility for 18 patients, and another or an unknown location for 16 patients (Table 2). Only 58 of the 117 sudden cardiac deaths from tachyarrhythmia occurring in the home (49.6%) were witnessed. Sudden cardiac

Subgroup	No. of Patients	Hazard Ratio (95% CI)	P Value for Interaction
All patients	7001	0.97 (0.81–1.17)	
Sex			0.98
Female	1220	0.99 (0.66–1.47)	
Male	5781	0.98 (0.79–1.20)	
Age			0.57
<65 yr	4039	0.91 (0.66–1.26)	
≥65 yr	2962	1.02 (0.82–1.28)	
Race			0.23
Minority	795	• 0.74 (0.45–1.22)	
Nonminority	6206	1.02 (0.84–1.25)	
Country			0.86
United States	2036	0.92 (0.66–1.28)	
Canada	1891	0.95 (0.69–1.33)	
Australia or New Zealand	2034	1.11 (0.77–1.61)	
United Kingdom, Germany, or the Netherlands	1040	• 0.89 (0.53–1.51)	
VEF			0.59
≤35%	1438	0.99 (0.75–1.32)	
>35%	4187	0.91 (0.68–1.21)	
Not measured	1376	● 1.20 (0.76–1.90)	
Diabetes			0.04
No	5497	1.16 (0.92–1.47)	
Yes	1504	● 0.77 (0.57–1.05)	
NYHA class			0.36
l or ll	6623	1.01 (0.82–1.24)	
III or IV	378	0.81 (0.54–1.21)	
Previous CABG			0.50
No	5134	0.92 (0.73–1.16)	
Yes	1867	1.05 (0.77–1.41)	
Education of spouse or companion			0.22
Did not complete secondary school	1319	0.79 (0.54–1.16)	
Completed secondary school	5682	1.04 (0.84–1.28)	
Employment status of patient	5002		0.96
Full-time	2284	↓ 1.01 (0.56−1.81)	0.50
Part-time	697	↓ 0.89 (0.41−1.92)	
Not employed	4020		
Duration of QRS interval	1020		0.66
<120 msec	6214	0.99 (0.79–1.22)	0.00
>120 msec	724	1.09 (0.74–1.60)	
Type of myocardial infarction	, 27		0.19
Anterior non-Q-wave	2491	1.13 (0.85–1.51)	5.17
Anterior Q-wave	4509		
	4305	0.5 1.0 2.0	
		AED Group Control Group	
		Better Better	

No subgroup was identified in which the outcome differed significantly from the primary findings. CABG denotes coronary-artery bypass grafting, LVEF left ventricular ejection fraction, and NYHA New York Heart Association.

Variable	Control Group (N=3506)	AED Group (N=3495)	Hazard Ratio (95% CI)†
Death from all causes — no. (%)	228 (6.5)	222 (6.4)	0.97 (0.81–1.17)
Onset at home	93 (40.8)	91 (41.0)	
Witnessed	51 (22.4)	54 (24.3)	
Tachyarrhythmia	34 (14.9)	29 (13.1)	
Cause of death — no. (%)			
Cardiac plus unknown events	139 (61.0)	141 (63.5)	1.01 (0.80–1.28)
Cardiac	129 (56.6)	138 (62.2)	1.07 (0.84–1.36)
Tachyarrhythmia	84 (36.8)	85 (38.3)	1.01 (0.75–1.37)
Heart failure	28 (12.3)	36 (16.2)	1.28 (0.78–2.10)
Nonarrhythmia	16 (7.0)	16 (7.2)	1.00 (0.50–2.00)
Not classifiable	1 (0.4)	1 (0.5)	
Noncardiac	89 (39.0)	81 (36.5)	0.91 (0.67–1.23)
Vascular	22 (9.6)	15 (6.8)	
Nonvascular	67 (29.4)	65 (29.3)	
Not classifiable	0	1 (0.5)	
Unknown cause	10 (4.4)	3 (1.4)	
Death from tachyarrhythmia — no.			
Sudden	78	82	
Onset location			
Home	60	57	
Home, witnessed	31	27	
Public place or work	5	4	
Hospital or long-term care facility	8	10	
Other or unknown	5	11	
Nonsudden	5	3	
Unknown	1	0	
Resuscitated cardiac arrest — no.			
Total events	19	19	
Onset location			
Home	8	8	
Home, witnessed	6	7	
Public place or work	2	1	
Hospital or long-term care facility	6	9	
Other or unknown	3	1	

* Percentages are based on the number of deaths. AED denotes automated external defibrillator, and CI confidence interval. † The hazard ratio is for the AED group as compared with the control group.

deaths from tachyarrhythmia that occurred at home and were witnessed comprised 12.9% of all deaths and 36.3% of the sudden cardiac deaths from tachyarrhythmia. There were no significant differences between the study groups in the location of the patient at the time of death.

RESUSCITATED CARDIAC ARREST

Thirty-eight patients were resuscitated from sudden cardiac arrest and survived for at least 48 hours (Table 2). Among 19 resuscitations in the control group, 8 occurred at home, 2 in a public place, 6 in a hospital or chronic care facility, and 3 in another or an unknown location. Among 19 resuscitations in the AED group, 8 occurred at home, 1 in a public place, 9 in a hospital or chronic care facility, and 1 in another location.

USE OF AN AED

During the trial, a study AED was applied to 32 patients in the AED group; of these patients, 29 were found unresponsive by a spouse, companion, or other household member. Correlative documentation of AED rhythms was available for 21 of 29 unresponsive patients (Fig. 3).

A shock was advised for confirmed ventricular fibrillation in 13 patients and was delivered in 12 of them. Of the 12 patients, 4 were longterm survivors, and another survived to hospital admission but died several days later. No shock was delivered in 1 of the 13 patients with ventricular fibrillation because a household member (not a spouse or companion) accidentally turned off the AED after the shock advisory. (This advisory was a verbal prompt from the AED to press the shock button; the power button was depressed inadvertently instead.) Of the remaining seven patients with ventricular fibrillation who died. AED shocks terminated ventricular fibrillation either to asystole or to a nonshockable rhythm. Monomorphic ventricular tachycardia was not identified in any patient.

A no-shock advisory was confirmed on the AED for eight of the unresponsive patients; of these patients, seven died, with a rhythm documented as asystole in five, complete heart block in one, and sinus tachycardia in one. One of the eight patients had sinus bradycardia and survived.

Of the 29 patients who were unresponsive, 8 did not have correlative AED rhythm information, but clinical information confirmed that an AED shock was delivered in 2 patients, both of whom died. Of the remaining 6 patients, 3 died and 3 had syncope from noncardiac causes and survived.

A no-shock advisory was given in the 3 patients who did not lose consciousness. There were no documented inappropriate shocks. Overall, 4 of the 14 patients with ventricular fibrillation (28.6%) who received an AED shock were longterm survivors.

GOOD SAMARITAN USE OF AED

Over the course of the trial, the AED was known to have been used in seven persons having sudden cardiac arrest who were not participating in the HAT trial but were neighbors or visitors to the patients' homes. In three such cases, no shock was advised and all three persons died. In four cases, a shock was advised and terminated ventricular fibrillation, with two persons surviving beyond hospital discharge.

DISCUSSION

In the HAT trial, we found that a strategy of placing an AED in the home did not reduce overall mortality in patients with a previous anteriorwall myocardial infarction who did not have an indication for implantation of a cardioverter-defibrillator, as compared with standard response training for cardiac arrest. Several factors may explain this finding. First, the overall mortality and the incidence of sudden cardiac arrest were much lower than predicted from historical data.13-15 This factor is probably a reflection of the efficacy and high level of use of modern drug therapy and the high rate of previous revascularization (72.2%) in the trial patients. As a result of these factors, the trial had substantially less power than initially projected. These effects were so profound that even a doubling in the population size would not have been sufficient to show an overall mortality benefit with home AED therapy. Remarkably, the enrolled patients were as likely to die from noncardiac causes (37.8% of deaths) as from sudden cardiac arrest from tachyarrhythmia (35.6%), with an annual risk of sudden cardiac arrest of less than 1% per year.

The training of the patients and their spouses or companions may have been an additional factor limiting the likelihood of a demonstrable benefit. All participants in the control group received resuscitation training, with frequent reminders; such education is not reflective of real-world instruction after myocardial infarction. At the same time, less than half the patients with sudden cardiac arrest at home had a witnessed event, and not all of them had the AED applied. This latter finding is particularly disconcerting, given the effort to inform partners or companions of the significance of AED use. Although the reasons for failure to deploy the AED are unclear, it is possible that a more aggressive AED reminder and retraining program might be required to ensure that lay rescuers would use the AED in a highly stressful situation. Such a program, how-

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ever, would exceed the practical limits of a public health study, both in terms of personnel time and cost. Furthermore, to contend with events occurring when the patient is asleep or alone, it is conceivable that some form of a home automated alert system might be of value, but no such system is currently available.³⁰

The successful delivery of a defibrillating shock in 14 patients and in 4 neighbors resulted in long-term survival for 6 (33%). This confirms that the use of an AED in the home or environs on loved ones or neighbors by lay users with minimal training is feasible, terminates ventricular fibrillation, and appears to carry no risk of inappropriate shock. The observed overall survival after sudden cardiac arrest in the home of 12.0% (18.3% for witnessed events) was significantly better than the figure of 2% that has previously been reported in the general population at home¹¹ and better than the 6% performance provided by emergency medical services in general.31 However, the low event rate and the neutral outcome with respect to death from any cause suggest that the placement of AEDs in homes would be an inefficient strategy in public health terms, despite the value to patients who are fortunate enough to have the event witnessed and the AED applied.

It is important to recognize that our trial results may not apply to the use of AEDs in higherrisk populations. Candidates for implantation of a cardioverter-defibrillator were excluded from our trial, although physicians' judgment and a variety of practice patterns in the enrolling countries resulted in the inclusion of some patients who might otherwise have satisfied criteria for use of an implantable cardioverter-defibrillator in the Sudden Cardiac Death in Heart Failure trial or the Multicenter Automatic Defibrillator Implantation Trial II (Table 1).16-19 It is nonetheless possible that a population with a higher event rate and a greater proportion of sudden deaths from tachyarrhythmia might benefit from access to a home AED.

Although the performance of AEDs in this trial may seem at odds with that reported for public-access defibrillation, one must remember that the denominator of patients in our trial was precisely defined, whereas that for public-access defibrillation was not clear. For example, the annual passenger volume in Chicago's O'Hare airport now exceeds 76 million, and this massive

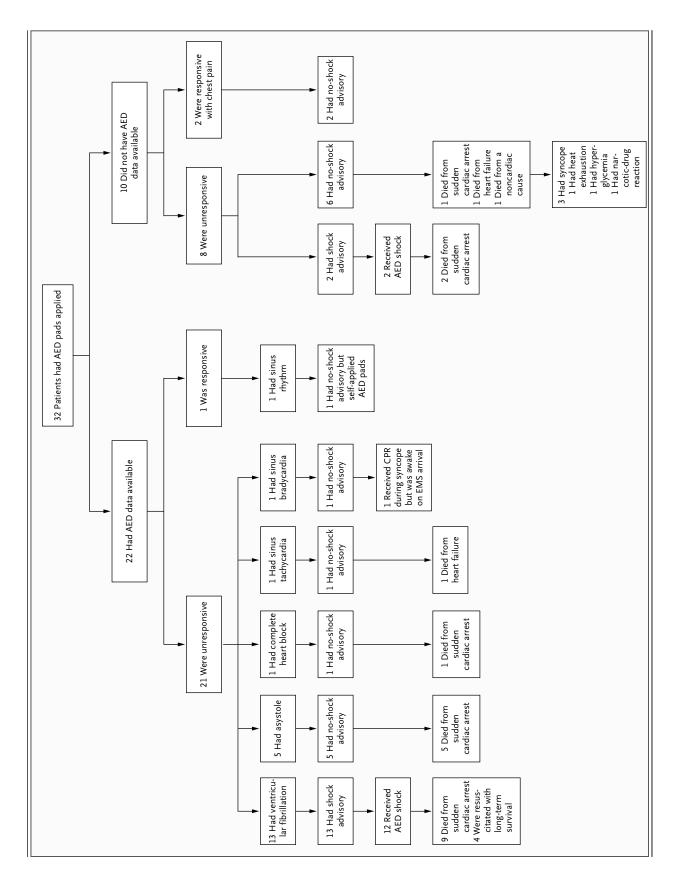
Figure 3 (facing page). Events and Outcomes Associated with the Use of an Automatic External Defibrillator (AED) in 32 Patients.

Of the 32 patients for whom an AED was applied, 29 were unresponsive. Of these patients, 13 were documented to be in ventricular fibrillation by review of the AED electrogram, and a shock was advised by the AED in each case. Two patients who were found in cardiac arrest had a shock advisory, apparently for ventricular fibrillation, although no recordings were available for review. Shocks terminated ventricular fibrillation in all 12 patients for whom an AED shock was given. (One rescuer who was not a spouse or companion accidentally turned off the device.) Of 14 patients for whom an AED shock was advised and delivered, 4 (28.6%) survived long term. Of 17 patients who had a no-shock advisory, 14 were unresponsive: 7 died from cardiac arrest, 2 died from heart failure, 1 died from a noncardiac cause, and 4 had syncope and survived. Three patients never lost consciousness, and either they applied the pads to themselves or a spouse applied them. In patients for whom data regarding the AED were unavailable, the AED status was determined by data forms and event narratives from site personnel. EMS denotes emergency medical services.

cohort is exposed to AEDs placed throughout the airport at a distance of 1 minute's walk apart.⁸ No clinical trial of the use of AEDs could assemble a denominator representing even 1% of that volume. Furthermore, in a public venue, there is the opportunity to use an AED in treating any one of many persons at risk. This factor contrasts with the home AED strategy, in which there is the opportunity to treat only those in the immediate household or environs.

The survival of some patients with sudden cardiac arrest who were treated early with AEDs in public settings is generally taken as proof of concept that the therapy is effective, since sudden cardiac arrest is known to have a rate of death approaching 100% with conventional resuscitation methods. However, such uses of AEDs are not an efficient attack on the public health problem of sudden cardiac arrest in moderaterisk populations, since most at-risk patients do not spend a sufficient portion of each day in public locations.

In conclusion, our trial evaluated the benefit of the availability of AEDs in the homes of patients with a previous anterior-wall myocardial infarction who were not otherwise candidates for implantation of a cardioverter-defibrillator. There was no significant reduction in death from any cause with a home AED. The very low event rate,



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the high proportion of unwitnessed events, and the underuse of AEDs in emergencies, rather than a lack of device efficacy, appear to explain these results.

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