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Sudden Death in Patients with Myocardial Infarction and Left Ventricular Dysfunction, Heart Failure, or Both

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ABSTRACT

BACKGROUND

The risk of sudden death from cardiac causes is increased among survivors of acute myocardial infarction with reduced left ventricular systolic function. We assessed the risk and time course of sudden death in high-risk patients after myocardial infarction.

METHODS

We studied 14,609 patients with left ventricular dysfunction, heart failure, or both after myocardial infarction to assess the incidence and timing of sudden unexpected death or cardiac arrest with resuscitation in relation to the left ventricular ejection fraction.

RESULTS

Of 14,609 patients, 1067 (7 percent) had an event a median of 180 days after myocardial infarction: 903 died suddenly, and 164 were resuscitated after cardiac arrest. The risk was highest in the first 30 days after myocardial infarction — 1.4 percent per month (95 percent confidence interval, 1.2 to 1.6 percent) — and decreased to 0.14 percent per month (95 percent confidence interval, 0.11 to 0.18 percent) after 2 years. Patients with a left ventricular ejection fraction of 30 percent or less were at highest risk in this early period (rate, 2.3 percent per month; 95 percent confidence interval, 1.8 to 2.8 percent). Nineteen percent of all sudden deaths or episodes of cardiac arrest with resuscitation occurred within the first 30 days after myocardial infarction, and 83 percent of all patients who died suddenly did so in the first 30 days after hospital discharge. Each decrease of 5 percentage points in the left ventricular ejection fraction was associated with a 21 percent adjusted increase in the risk of sudden death or cardiac arrest with resuscitation in the first 30 days.

CONCLUSIONS

The risk of sudden death is highest in the first 30 days after myocardial infarction among patients with left ventricular dysfunction, heart failure, or both. Thus, earlier implementation of strategies for preventing sudden death may be warranted in selected patients.

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SUDDEN DEATH IS A CATASTROPHIC COMPLICATION of acute myocardial infarction.¹ Although many patients who die from an acute myocardial infarction do so before reaching the hospital, those admitted remain at substantial risk for ventricular arrhythmias. That risk is greatest in the first few hours, declines rapidly thereafter, and is influenced by the extent of myocardial injury, recurrent ischemia, electrolyte abnormalities, and other factors.^{2,3} The success of coronary care units in the 1960s was, in part, related to the early identification and treatment of life-threatening arrhythmias that occurred in the setting of an acute myocardial infarction. Though the risk of sudden death is believed to decrease rapidly after infarction, the extent and time course of this change in risk have not been well studied, especially since the use of coronary reperfusion, beta-blockers, and angiotensin-converting-enzyme inhibitors has become widespread.

Reduced left ventricular function is a major risk factor for death, including sudden death, after myocardial infarction.^{4,5} This observation has led to trials of implantable cardioverter-defibrillators (ICDs) in patients with a low left ventricular ejection fraction after infarction.⁶ The Multicenter Unsustained Tachycardia Trial (MUSTT) demonstrated the benefit of an ICD in patients with coronary artery disease, a left ventricular ejection fraction of 40 percent or less, and inducible sustained ventricular tachycardia.⁷ The Multicenter Automatic Defibrillator Implantation Trial II (MADIT-II)⁸ further showed a benefit of empirical ICD therapy in patients with a left ventricular ejection fraction of 30 percent or less one month or more after myocardial infarction. Although these studies enrolled few patients within six months after they had had a myocardial infarction, the results are reflected in the current American College of Cardiology–American Heart Association guidelines for the management of acute myocardial infarction,⁹ which recommend the implantation of an ICD one month or more after myocardial infarction in patients with a left ventricular ejection fraction of 30 percent or less and in those with a left ventricular ejection fraction of 40 percent or less and additional evidence of electrical instability. In contrast, the recently reported Defibrillator in Acute Myocardial Infarction Trial (DINAMIT)¹⁰ did not show that the implantation of an ICD 6 to 40 days after myocardial infarction reduced the risk of death in patients with a left ventricular ejection fraction of 35 percent or less and reduced heart-rate variability. Nevertheless, the risk

of sudden death in the early period after myocardial infarction remains high and has not been well studied in the modern era.¹¹ To better delineate the early and later risk of sudden death after myocardial infarction and the association of these risks with the left ventricular ejection fraction, we studied patients enrolled in the Valsartan in Acute Myocardial Infarction Trial (VALIANT).

METHODS

VALIANT was a randomized, controlled trial of treatment with valsartan, captopril, or both in 14,703 patients with a first or subsequent acute myocardial infarction complicated by heart failure, left ventricular systolic dysfunction, or both.¹² Patients were enrolled between December 1998 and June 2001. All patients had an ejection fraction of no more than 40 percent or clinical or radiologic evidence of heart failure complicating their myocardial infarction. For this analysis, we excluded 94 patients because they had already received an ICD before randomization. All patients gave written informed consent, and the research protocol was approved by the appropriate review boards. The details of the patient population and the protocol, including inclusion and exclusion criteria, have been reported previously.¹²

A central adjudication committee reviewed all deaths and episodes of cardiac arrest with resuscitation in a blinded fashion, using source documentation provided by the site investigators. Deaths were classified as having cardiovascular or noncardiovascular causes, and deaths from cardiovascular causes were further classified as sudden or due to myocardial infarction, heart failure, stroke, or another cardiovascular cause. Sudden death was explicitly defined as death that occurred “suddenly and unexpectedly” in a patient in otherwise stable condition and included witnessed deaths (with or without documentation of arrhythmia) and unwitnessed deaths if the patient had been seen within 24 hours before death but had not had premonitory heart failure, myocardial infarction, or another clear cause of death. Cardiac arrest with resuscitation was defined as cardiac arrest from which a patient regained consciousness and subsequent cognitive function, even briefly.

The median duration of follow-up was 24.7 months. Sudden deaths and episodes of cardiac arrest with resuscitation were combined for this analysis. The left ventricular ejection fraction was determined before randomization (a median of five

days after myocardial infarction) at the clinical site in 11,256 patients: echocardiography was used in 9095, radionuclide ventriculography in 272, and contrast ventriculography in 1889. The analysis of the incidence and timing of sudden death included all patients and was related to the left ventricular ejection fraction in the subgroup of patients for whom information on the ejection fraction was available: 3852 with an ejection fraction of 30 percent or less, 4998 with an ejection fraction of 31 to 40 percent, and 2406 with an ejection fraction of more than 40 percent.

The rates of sudden death were assessed by dividing the events in each period by the number of person-days of exposure and are expressed as the percentage per month. Baseline clinical characteristics were compared with the use of Student's *t*-test for continuous variables and the chi-square test for categorical variables. The risk of sudden death associated with each decrease of 5 percentage points in the left ventricular ejection fraction was assessed in a Cox proportional-hazards model, with adjustment for all known baseline covariates.

RESULTS

Of 14,609 patients, 1067 (7 percent) had an event: 903 patients died suddenly, and 164 were resuscitated after cardiac arrest. For 643 of the 1067 patients (60 percent), this was the first cardiovascular event after enrollment. Five patients who were resuscitated after cardiac arrest died on the day of resuscitation. The median time to sudden death or cardiac arrest with resuscitation was 180 days after myocardial infarction (interquartile range, 50 to 428). Of the 164 patients who were resuscitated, 108 (66 percent) were alive at six months and 93 (57 percent) were alive at the end of the trial. As compared with surviving patients without events, patients who died suddenly or had cardiac arrest with resuscitation were significantly older; had higher baseline systolic and diastolic blood pressures, baseline heart rate, and Killip class; had a lower left ventricular ejection fraction; were more likely to have a history of diabetes or hypertension; and were less likely to have been treated with reperfusion therapy, amiodarone, or beta-blockers (Table 1). The differences between patients who died suddenly or were resuscitated after cardiac arrest and those who died of other causes were much less clinically apparent.

During the first 30 days after myocardial infarction, 126 patients died suddenly and 72 patients

were resuscitated after cardiac arrest (representing 19 percent of all patients with such events during the trial), for an event rate of 1.4 percent per month (95 percent confidence interval, 1.2 to 1.6 percent). Eighty-three percent of sudden-death events from which the patients were not resuscitated occurred after hospital discharge. Of the patients who were resuscitated during the first 30 days after myocardial infarction, 74 percent were alive at 1 year. Event rates and the cumulative incidence of events during various periods in the study are shown in Table 2. The rate of sudden death or cardiac arrest with resuscitation decreased precipitously during the first year, declining to 0.14 percent per month (95 percent confidence interval, 0.11 to 0.18 percent) after year 2.

Figure 1 shows the Kaplan–Meier estimates of the rate of sudden death or cardiac arrest with resuscitation according to the left ventricular ejection fraction in patients in whom the ejection fraction was measured. The increased early incidence of these events was most apparent among patients with an ejection fraction of 30 percent or less: the incidence rate during the first 30 days was 2.3 percent per month (95 percent confidence interval, 1.8 to 2.8 percent) (Fig. 1 and 2). Of the 156 sudden deaths or episodes of cardiac arrest with resuscitation that occurred during the first 30 days, 85 occurred among the 3852 patients with an ejection fraction of 30 percent or less (54 percent; 1 percent of all patients with a known left ventricular ejection fraction). Of the 3852 patients with an ejection fraction of 30 percent or less, 399 (10 percent) died suddenly or had cardiac arrest with resuscitation during the trial, as compared with 295 of the 4998 patients with an ejection fraction of 31 to 40 percent (6 percent) and 119 of the 2406 patients with an ejection fraction of more than 40 percent (5 percent). Among the patients with a known left ventricular ejection fraction, 49 percent of all sudden deaths or cardiac arrests with resuscitation occurred in patients with an ejection fraction of 30 percent or less, and this proportion remained relatively constant throughout follow-up.

Among the 399 patients with an ejection fraction of 30 percent or less who died suddenly or had cardiac arrest with resuscitation, 85 (21 percent) did so during the first 30 days after myocardial infarction, as compared with 50 of 295 such patients with an ejection fraction of 31 to 40 percent (17 percent) and 21 of 119 such patients with an ejection fraction of more than 40 percent (18 percent). Nevertheless, even among patients with an ejection frac-

Table 1. Baseline Characteristics of the Patients, According to the Outcome.*

| Characteristic | Sudden Death or Cardiac Arrest with Resuscitation (N=1067) | Death from Cause Other Than Sudden Death (N=1905) | P Value | Survival Free of Sudden Death or Cardiac Arrest with Resuscitation (N=11,637) | P Value† |
|---|--|---|---------|---|----------|
| Age (yr) | 67.8±11.2 | 71.4±10.3 | <0.001 | 63.5±11.7 | <0.001 |
| Male sex (%) | 67 | 61 | 0.002 | 70 | 0.04 |
| Blood pressure (mm Hg) | | | | | |
| Systolic | 125.1±18.2 | 123.5±17.5 | 0.02 | 122.3±17.0 | <0.001 |
| Diastolic | 73.3±12.0 | 71.9±11.9 | 0.002 | 72.3±11.1 | 0.008 |
| Heart rate (beats/min) | 78.1±13.6 | 78.9±13.7 | 0.10 | 75.6±12.5 | <0.001 |
| Body-mass index | 27.7±5.7 | 27.1±5.0 | 0.007 | 28.0±5.3 | 0.04 |
| Killip class (%) | | | 0.13 | | <0.001 |
| I | 19 | 17 | | 30 | |
| II | 46 | 47 | | 49 | |
| III | 26 | 26 | | 15 | |
| IV | 9 | 10 | | 5 | |
| Clinical or radiologic evidence of CHF at entry (%) | 83 | 85 | 0.10 | 75 | <0.001 |
| Prior myocardial infarction (%) | 45 | 41 | 0.08 | 24 | <0.001 |
| History of hypertension (%) | 64 | 64 | 0.96 | 53 | <0.001 |
| History of diabetes (%) | 31 | 32 | 0.42 | 21 | <0.001 |
| Beta-blocker (%) | 61 | 57 | 0.07 | 73 | <0.001 |
| Amiodarone (%) | 20 | 19 | 0.73 | 8 | <0.001 |
| Primary PCI (%) | 8 | 8 | 0.34 | 17 | <0.001 |
| Thrombolytic therapy (%) | 24 | 25 | 0.32 | 38 | <0.001 |
| Primary PCI or thrombolytic therapy (%) | 30 | 32 | 0.25 | 49 | <0.001 |
| LVEF | 0.32±0.10 | 0.33±0.10 | 0.06 | 0.36±0.10 | <0.001 |

* Plus-minus values are means ±SD. The body-mass index is the weight in kilograms divided by the square of the height in meters. Percentages may not sum to 100 because of rounding. CHF denotes congestive heart failure, PCI percutaneous coronary intervention, and LVEF left ventricular ejection fraction.

† P values are for the comparison with sudden death or cardiac arrest with resuscitation.

tion of more than 40 percent, the rate of sudden death or cardiac arrest with resuscitation was more than six times as high in the first month as after one year. Although the incidence of sudden death or cardiac arrest with resuscitation declined markedly over time in all groups, the relative risk of these events remained two to three times as high as among patients with a left ventricular ejection fraction of 30 percent or less as among patients with an ejection fraction of more than 40 percent, although overall, the absolute rate after two years was substantially lower than during the early period. When the left ventricular ejection fraction was considered as a continuous variable, each decrease of 5 percentage points in the ejection fraction was associated with a 21 percent increase in the risk of sudden

death or cardiac arrest with resuscitation during the first 30 days after myocardial infarction (hazard ratio, 1.21; 95 percent confidence interval, 1.10 to 1.30), after adjustment for all known baseline covariates.

DISCUSSION

The results of our analysis confirm that patients with left ventricular dysfunction, heart failure, or both after myocardial infarction are at high risk for sudden death or cardiac arrest with resuscitation. The absolute risk is greatest in the early period after myocardial infarction and among patients with the lowest ejection fraction and declines significantly over time, reaching a steady state at approximately

Table 2. Event Rate and Cumulative Incidence of Events during Follow-up.*

| Time after Myocardial Infarction | No. at Risk at Beginning of Interval | No. Who Died of Any Cause during Interval | Sudden Death or Cardiac Arrest with Resuscitation | | |
|----------------------------------|--------------------------------------|---|---|--------------------------|------------------------|
| | | | No. of Patients | Event Rate %/mo (95% CI) | Cumulative Incidence % |
| 0–30 Days | 14,609 | 589 | 198 | 1.4 (1.2–1.6) | 1.4 |
| >1–6 Mo | 13,997 | 767 | 340 | 0.50 (0.45–0.55) | 2.5 |
| >6–12 Mo | 13,157 | 509 | 211 | 0.27 (0.23–0.31) | 1.6 |
| >1–2 Yr | 12,622 | 754 | 240 | 0.18 (0.16–0.20) | 2.1 |
| >2–3 Yr | 7,926 | 244 | 75 | 0.14 (0.11–0.18) | 1.7 |

* CI denotes confidence interval.

one year. The risk was increased despite the fact that all patients, according to the study design, were receiving inhibitors of the renin–angiotensin system and the majority were receiving beta-blockers and aspirin.

Several measures may identify patients at highest risk for sudden death in the first year after myocardial infarction.^{3,13,14} These are an assessment of the frequency or severity of arrhythmia, including the incidence of premature ventricular contractions, nonsustained ventricular tachycardia, dispersion of the QT interval, and late potentials on signal-averaged electrocardiograms; measures of autonomic function; and the results of invasive electrophysiological testing.^{15–17} The left ventricular ejection fraction, an independent risk factor for sudden death, is currently the most widely used and robust clinical determinant of risk after infarction and has become the basis for determining a patient’s eligibility for ICD therapy.⁹ However, it is poor at distinguishing between patients who will die from arrhythmia and those who will die of other cardiovascular causes.¹⁸ In VALIANT, patients who died suddenly were similar to those who died of other causes. Other causes of death included pump failure, recurrent myocardial infarction, procedure-related causes, other cardiac causes, and noncardiac causes, which were relatively rare in this population. Baseline characteristics that were associated with an increased risk of death from other causes were also associated with an increased risk of sudden death. Our inability to distinguish patients who died suddenly from those who died of other causes may reflect our lack of more sophisticated measures of the risk of arrhythmia in this study.

The other key determinant of the risk of sudden

death is the time after myocardial infarction. The absolute risk of sudden death is highest in the first year after myocardial infarction. Our data suggest that this risk is greatest within the first week after myocardial infarction and falls rapidly within the first month. The increased early rate of sudden death was highest among patients with the lowest left ventricular ejection fraction, but the high incidence was not restricted to patients with the lowest left ventricular ejection fraction. Indeed, the incidence of sudden death in the group with the highest ejection fraction was greater in the first 30 days than was the incidence of sudden death in the group with the lowest ejection fraction after 90 days. Moreover, patients who died suddenly or had cardiac arrest with resuscitation were in clinically stable con-

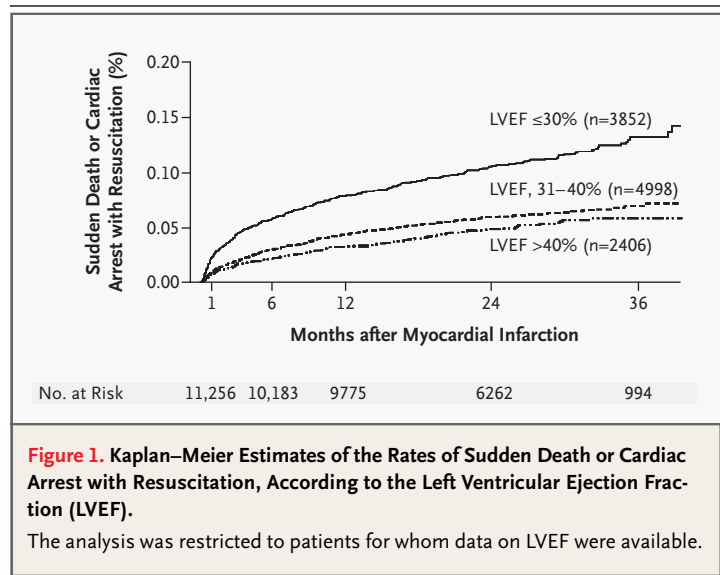
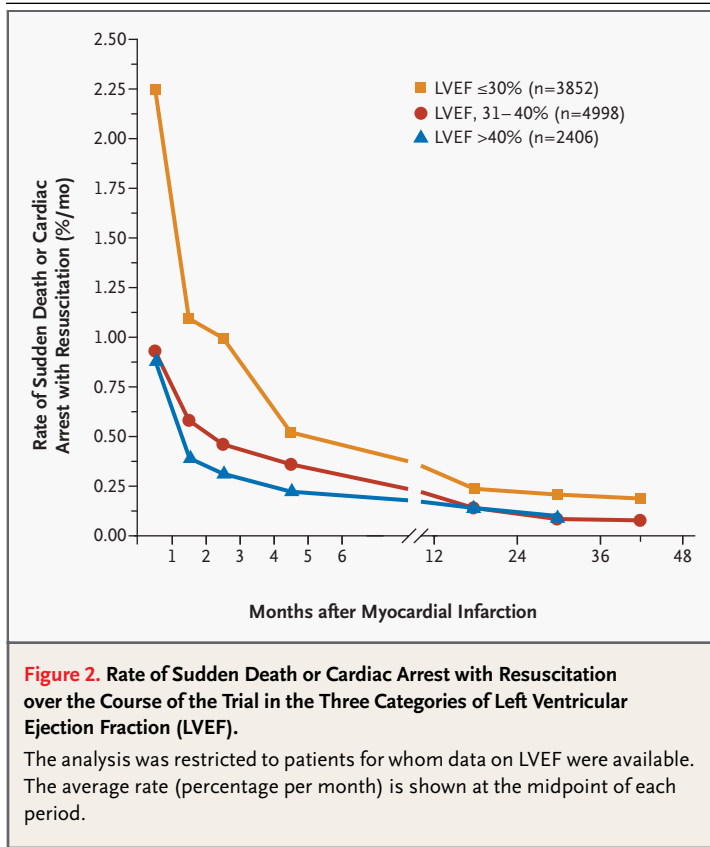


Figure 1. Kaplan–Meier Estimates of the Rates of Sudden Death or Cardiac Arrest with Resuscitation, According to the Left Ventricular Ejection Fraction (LVEF).

The analysis was restricted to patients for whom data on LVEF were available.



dition and many had recently been discharged from the hospital. Thus, to prevent sudden death after infarction, the ideal strategy must also take into account patients with a better-preserved left ventricular ejection fraction (more than 40 percent).

The discriminatory effect of the left ventricular ejection fraction appears to be greatest in the first six months after myocardial infarction. Among patients who survived beyond one year, the annualized rate of sudden death was still highest in the group with the lowest left ventricular ejection fraction but was fairly similar among the three ejection-fraction groups, although the relative risk remained higher in the groups with a lower ejection fraction. This observation, however, should be tempered by the fact that patients who survive are already at lower risk. Also, ventricular function was measured relatively early after infarction, and in some patients, substantial recovery of ventricular function may have occurred with a concomitant decrease in the risk of sudden death. An additional decline in the left ventricular ejection fraction may occur over time, and the risk of sudden death at a particular time after myocardial infarction is more likely to be related to

the ejection fraction at that time than to the ejection fraction in the periinfarction period.

Although our findings suggest that a strategy of treating a greater proportion of patients early and focusing on those with a low left ventricular ejection fraction later might be the most efficient approach to minimizing the risk of sudden death after myocardial infarction, the recently reported DINAMIT showed no benefit of implanting an ICD 6 to 40 days after myocardial infarction in patients with an ejection fraction of 35 percent or less and evidence of reduced heart-rate variability.¹⁰ Indeed, in that trial, a decrease in the rate of death from arrhythmia was offset by an increase in the rate of death from other causes.¹⁹ The DINAMIT findings thus did not provide support for the use of early ICD therapy in a high-risk population after myocardial infarction and underscore the fact that patients at increased risk for sudden death from arrhythmia are also at increased risk for death from other causes.

Although it is difficult to reconcile the absence of a benefit in DINAMIT with the substantially increased risk of sudden death we observed in the early post-infarction period, there were a number of important differences between the two studies. Although DINAMIT enrolled patients with a lower overall left ventricular ejection fraction than did VALIANT, the average time to enrollment was 18 days after myocardial infarction — 13 days later than the average enrollment date in VALIANT — and thus, DINAMIT may have selected for patients already at lower risk for sudden death. Moreover, at 7.2 percent per year, the overall mortality rate was lower in DINAMIT than in VALIANT. Although the rate of death from arrhythmia in the DINAMIT control group was similar to the rate of sudden death in VALIANT (3.5 percent and 3.7 percent per year, respectively), the true rate of death from arrhythmia in our study may have been much higher, since only unexpected deaths were categorized as sudden, thereby excluding patients with fatal arrhythmia in the setting of myocardial infarction or pump failure. Alternatively, DINAMIT, with only 120 deaths, may have been statistically underpowered to demonstrate a clinically important difference between groups, an interpretation that would suggest the need for additional studies of ways to prevent sudden death from arrhythmia in the early period after infarction.

It remains unclear whether therapies targeted at a high-risk population soon after infarction would reduce the risk of sudden unexpected death, but

our data provide a rationale for considering early-intervention strategies, including short-term therapies, in selected patients at risk. This is supported by the fact that the majority of our patients (74 percent) who were resuscitated during the first 30 days were alive at 1 year. In addition, although our data suggest that the overall risk of sudden death or cardiac arrest with resuscitation increases with a decreasing left ventricular ejection fraction, even in patients with an ejection fraction of more than 40 percent, the risk of sudden death or cardiac arrest with resuscitation was six times as high in the first 30 days as at 1 year, suggesting a potential role for early short-term intervention, even in lower-risk patients. For example, if all sudden deaths could be prevented, a strategy of treating everyone for 30 days and only those with a left ventricular ejection fraction of 30 percent or less beyond 30 days in the VALIANT study would potentially have prevented or postponed 507 deaths, as compared with 317 deaths with the use of the currently recommended strategy of treating only those with an ejection fraction of 30 percent or less beyond 30 days. This approach may not be practical on the basis of current ICD technology, but such an approach might be practical and cost-effective in the future, although it must be noted that current Medicare regulations do not allow for payment for ICD therapy before 40 days after myocardial infarction.⁶

A number of limitations of this analysis should be noted. First, the left ventricular ejection fraction was measured locally, not centrally, although local

estimation of the ejection fraction is used to make clinical decisions. Second, some patients identified as having died suddenly may have died from causes such as aortic dissection, pulmonary embolism, stroke, and especially, reinfarction; in the case of reinfarction, sudden death may still be due to arrhythmia.²⁰ Also, since our definition of sudden death specified prior stability, we may have excluded many deaths from arrhythmia that occurred in the setting of myocardial infarction or heart failure. Finally, although our data may help guide interventional strategies that reduce risk, we did not assess the efficacy of such strategies.

In summary, we demonstrated that the risk of sudden death is highest soon after myocardial infarction — particularly during the first 30 days. This risk is greatest among patients with the lowest left ventricular ejection fraction (30 percent or less), but even patients with a high ejection fraction (more than 40 percent) are at substantially increased risk in the early post-infarction period, as compared with the subsequent risk, and the discriminatory effect of the left ventricular ejection fraction declines over time. Although it is not known whether early ICD therapy would reduce these risks, taken in the context of recent data demonstrating the benefits of ICD therapy in high-risk patients,²¹ our data suggest the need to consider implementing strategies to prevent sudden death in selected patients before the time recommended by current guidelines.

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CORRECTION

Sudden Death in Patients with Myocardial Infarction and Left Ventricular Dysfunction, Heart Failure, or Both

Sudden Death in Patients with Myocardial Infarction and Left Ventricular Dysfunction, Heart Failure, or Both . On page 2581, lines 9 and 10 in the Results section of the Abstract should have stated that “83 percent of all patients who died suddenly in the first 30 days did so after hospital discharge,” rather than “83 percent of all patients who died suddenly did so in the first 30 days after hospital discharge,” as printed. We regret the error.