ORIGINAL ARTICLE

Trial of an Intervention to Improve Acute Heart Failure Outcomes

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ABSTRACT

BACKGROUND

Patients with acute heart failure are frequently or systematically hospitalized, often because the risk of adverse events is uncertain and the options for rapid follow-up are inadequate. Whether the use of a strategy to support clinicians in making decisions about discharging or admitting patients, coupled with rapid follow-up in an outpatient clinic, would affect outcomes remains uncertain.

METHODS

In a stepped-wedge, cluster-randomized trial conducted in Ontario, Canada, we randomly assigned 10 hospitals to staggered start dates for one-way crossover from the control phase (usual care) to the intervention phase, which involved the use of a point-of-care algorithm to stratify patients with acute heart failure according to the risk of death. During the intervention phase, low-risk patients were discharged early (in ≤3 days) and received standardized outpatient care, and high-risk patients were admitted to the hospital. The coprimary outcomes were a composite of death from any cause or hospitalization for cardiovascular causes within 30 days after presentation and the composite outcome within 20 months.

RESULTS

A total of 5452 patients were enrolled in the trial (2972 during the control phase and 2480 during the intervention phase). Within 30 days, death from any cause or hospitalization for cardiovascular causes occurred in 301 patients (12.1%) who were enrolled during the intervention phase and in 430 patients (14.5%) who were enrolled during the control phase (adjusted hazard ratio, 0.88; 95% confidence interval [CI], 0.78 to 0.99; P=0.04). Within 20 months, the cumulative incidence of primary-outcome events was 54.4% (95% CI, 48.6 to 59.9) among patients who were enrolled during the intervention phase and 56.2% (95% CI, 54.2 to 58.1) among patients who were enrolled during the control phase (adjusted hazard ratio, 0.95; 95% CI, 0.92 to 0.99). Fewer than six deaths or hospitalizations for any cause occurred in low- or intermediate-risk patients before the first outpatient visit within 30 days after discharge.

CONCLUSIONS

Among patients with acute heart failure who were seeking emergency care, the use of a hospital-based strategy to support clinical decision making and rapid follow-up led to a lower risk of the composite of death from any cause or hospitalization for cardiovascular causes within 30 days than usual care. (Funded by the Ontario SPOR Support Unit and others; COACH ClinicalTrials.gov number, NCT02674438.)

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*The complete list of COACH (Comparison of Outcomes and Access to Care for Heart Failure) Trial Investigators is provided in the Supplementary Appendix, available at NEJM.org.

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Heart failure affects approximately 26 million people worldwide and exerts substantial pressure on health care systems as a result of its high levels of associated morbidity and resource use.[1,2] A key indicator of the burden on patients with heart failure and on health systems is hospitalization; heart failure leads to more than 1 million hospital admissions and readmissions annually in the United States alone.[3] The 30-day risk of readmission and 30-day mortality associated with heart failure have not decreased substantively over time.[4,5] Consequently, new approaches to improve clinical decision making and care are needed if health systems are to improve outcomes for patients with heart failure.

The first point of medical contact for patients with acute heart failure is often the emergency department, where physicians have traditionally relied on clinical judgment to decide whether to discharge or admit their patients.[6] However, when such decisions are based on clinical judgment, some high-risk patients are discharged directly from the emergency department and then have early adverse events, including death.[7] Conversely, some low-risk patients are admitted when they could have been discharged and monitored in an outpatient clinic.[7] One of the barriers to early discharge of low-risk patients is the lack of access to transitional care, which could include follow-up outpatient care with a cardiac specialist during the vulnerable period after discharge; the lack of access to transitional care may contribute to a high risk of readmission.[8,9]

In the Comparison of Outcomes and Access to Care for Heart Failure (COACH) trial, we assessed a strategy to support clinical decision making, which involved the use of a tool for objective risk stratification in the emergency department, combined with the provision of standardized transitional care when indicated for patients with heart failure. Our objective was to determine whether this strategy led to better clinical outcomes than usual care, which involved the use of clinical judgment and estimation of risk for decision making, as well as nonstandardized routine follow-up after discharge.

Methods

Trial Design

The COACH trial was a cross-sectional, stepped-wedge, cluster-randomized trial[10,11] that was conducted in 10 hospitals in Ontario, Canada. A list of participating sites is provided in the Supplementary Appendix, available with the full text of this article at NEJM.org. Because the trial evaluated a hospital-level intervention that required the involvement of multiple disciplines, randomization was performed at the hospital level. The stepped-wedge, cluster-randomized design was chosen to facilitate recruitment and implementation of the intervention at all participating sites.[11]

A Quick Take is available at NEJM.org

Each hospital was randomly assigned to a sequence that indicated the period (cluster) during which crossover from the control phase to the intervention phase would occur. There were five sequences and six periods, with each period having a duration of 4 months (Fig. S1 in the Supplementary Appendix). A covariate-constrained randomization method[12] was used to allow balance between patients who were enrolled during the intervention phase and those who were enrolled during the control phase with regard to status as a teaching hospital (there were five academic hospitals and five community hospitals) and the annual volume of patients with heart failure.[10] An independent statistician implemented the randomization scheme.[13] All research personnel and hospitals were unaware of the hospital sequence assignments until 4 months before implementation of an intervention; at that point, staff were informed about the intervention, and the implementation team performed training before crossover.

Some of the material presented here is based on data and information compiled and provided by the Canadian Institute for Health Information and the Ontario Ministry of Health. Details regarding the trial design are provided in the protocol, available at NEJM.org.

Trial Population

Patients were eligible for enrollment in the trial if they were at least 18 years of age and presented to the emergency department with acute heart failure. The clinical diagnosis of heart failure was verified with data from the hospital record and was based on the emergency department face sheet showing a primary diagnosis code of I50 from the *International Classification of Diseases, 10th Clinical Canadian Modification*.[10]

The following patients were excluded: patients who did not have a clinical diagnosis of heart failure according to Framingham Heart Study criteria or had a B-type natriuretic peptide

level that indicated that the diagnosis was unlikely (i.e., a B-type natriuretic peptide level of <100 pg per milliliter or an N-terminal pro–B-type natriuretic peptide level of <300 pg per milliliter)[10]; patients who had end-stage disease or were receiving palliative care, because they were not eligible for risk estimation with the use of the Emergency Heart Failure Mortality Risk Grade for 30-day mortality (EHMRG30-ST)[14,15]; patients whose data could not be linked to databases because of an invalid health-card number; patients who were unable to attend visits in an outpatient clinic (i.e., those who had limited mobility or dementia or were nursing-home residents), because greater burden would be placed on the patient if care was shifted to the outpatient setting as part of participation in the trial; and patients who did not have a permanent home address, those who were not residents of Ontario, Canada, and those who left the hospital against medical advice, because of logistic difficulties with scheduling multiple outpatient visits (Table S1). Research ethics approval was obtained at all participating hospitals, and the requirement for informed consent was waived to allow for the inclusion of patients regardless of language and other potential barriers to trial participation.

Trained chart abstractors, who were unaware of the hospital sequence assignments, obtained detailed clinical information from hospital records — including demographic characteristics, presenting signs and symptoms, medical history, left ventricular function, and laboratory test results and biomarker levels — and confirmed the clinical diagnosis of heart failure with data from hospital records for all trial participants. With the use of government-issued health-card numbers, trial participants were linked to administrative databases that provided information about hospitalizations (Canadian Institute for Health Information Discharge Abstract Database), emergency department visits (National Ambulatory Care Reporting System), physician claims (Table S2), and vital status for all residents of the province (Registered Persons Database).[16] These data sets were linked with the use of unique encoded identifiers and analyzed at ICES (formerly the Institute for Clinical Evaluative Sciences). The use of data in this project was authorized under section 45 of the Ontario Personal Health Information Protection Act.

TRIAL INTERVENTION

The trial intervention consisted of a strategy to support clinicians in making decisions about discharging or admitting patients who presented to the emergency department with acute heart failure. A previously derived and validated point-of-care tool for risk stratification (EHMRG30-ST)[14,15,17] was made available to clinicians (Tables S3 through S6). The EHMRG30-ST tool was housed on a central server at ICES and was made accessible to Internet portal addresses at participating hospitals only after crossover to the intervention phase. During the intervention phase, hospital staff could use a secure Web interface to access the EHMRG30-ST tool in order ascertain whether patients had a low, intermediate, or high risk of death within 7 days or within 30 days (Fig. S2).

Patients who had a low risk of both death within 7 days and death within 30 days were recommended to be discharged early and to receive standardized transitional care, and patients who had a high risk were recommended to be admitted to the hospital. Clinicians were advised to use clinical judgment for patients who had an intermediate risk, but the general guidance was to admit patients who had an intermediate-to-high risk and to consider early discharge for patients who had a low-to-intermediate risk. Early discharge was defined as either discharge directly from the emergency department or discharge after an observation period in the hospital of up to 3 days. Patients who were discharged early were given access to standardized transitional care in the Rapid Ambulatory Program for Investigation and Diagnosis of Heart Failure (RAPID-HF) clinic. The RAPID-HF clinic was staffed by a nurse and supervised by a cardiologist, and the clinic provided outpatient care for up to 30 days after discharge from the emergency department or hospital, as described previously (Tables S7 through S9 and Fig. S3).[10,18]

TRIAL OUTCOMES

Two coprimary outcomes were specified (Table S10). The first coprimary outcome was a composite of death from any cause or hospitalization for cardiovascular causes within 30 days after presentation to the emergency department, evaluated in a time-to-event analysis (i.e., early outcome).[10] The second coprimary outcome was the composite outcome within 20 months (600 days) after presentation (i.e., extended outcome). The

coprimary outcomes in our trial differed from the original outcomes (death or hospitalization for any cause) that were proposed when the trial was conceived during application for funding, because in preparation for the trial, we found that among patients who had a shorter hospital admission, the risk of hospitalization for cardiovascular causes was increased during the early period after discharge, whereas no relationship with the risk of hospitalization for any cause during that period was present.[19]

Hospitalizations for cardiovascular causes that occurred after the index presentation (and after the index hospital admission if indicated), were not elective, and were longer than 1 day were counted as primary-outcome events. A hospitalization could not be counted as both an index event and a primary-outcome event. If a hospitalization or death occurred during the intervention phase but the index presentation occurred during the control phase, the primary-outcome event was attributed to the control phase.

Secondary outcomes included each of the following outcomes (evaluated in time-to-event analyses): hospitalization for cardiovascular causes, hospitalization for heart failure, and death from any cause. Because the EHMRG30-ST tool cannot be used to estimate risk in patients who are receiving palliative care, and because patients with heart failure may opt for palliative care during extended follow-up, mortality data were obtained until patients were transitioned to palliative care (e.g., symptom control or comfort care) in accordance with previously published and validated methods (Table S11).[20] A secondary outcome that was chosen by the patient advisory panel was a composite of the first nonelective emergency department visit, death from any cause, or hospitalization for cardiovascular causes, evaluated in a time-to-event analysis.[21] Serious adverse events were defined as death or hospitalization for either cardiovascular causes or any cause that occurred in low- or intermediate-risk patients after early discharge and before the first outpatient visit.

STATISTICAL ANALYSIS

Power calculations were based on the analysis of ICES data regarding patients with heart failure, which showed a baseline risk of primary-outcome events of 65% at 1 year after presentation to the emergency department. We calculated that a stepped-wedge design with a sample of 10 hospitals (2 hospitals randomly assigned to each of the five sequences) and a mean of 145 patients per period (a total of 8700 patients over the six periods, including patients at hospitals in the control phase and those at hospitals in the intervention phase in each period) provided the trial with 85% power to detect a clinically important relative difference of 10%, at a two-sided alpha level of 0.05. Our calculation was performed under the assumption of an intracluster correlation coefficient of 0.01 (based on the analysis of ICES data) and with the use of a discrete exponential decay model to allow for 20% decay in the strength of the correlation per period. No adjustment was made for cluster attrition because the risk of attrition was extremely low and all outcome data were to be collected routinely, regardless of any dropout.

The coprimary and secondary outcomes were analyzed with the use of Cox proportional-hazards models, with adjustment for period to account for any secular trend and with robust variance estimation to account for clustering according to hospital.[10] We entered time as steps (with each step being a 4-month interval of time) as fixed effects into the model to account for period effects. The analyses were also adjusted for status as a teaching hospital and the annual volume of patients with heart failure, the factors used in covariate-constrained randomization.[10] Binary outcomes were compared with the use of logistic-regression models, generalized estimation equation methods to account for within-hospital clustering, the small-sample correction method of Kauermann and Carroll (because the number of sites in the trial was not large), and further adjustment for period, status as a teaching hospital, and the annual volume of patients with heart failure.[22] Cumulative-incidence curves from adjusted and unadjusted analyses of outcomes were constructed as appropriate. Censoring of data occurred at 30 days or 20 months or on the last day of the study follow-up period (January 15, 2019). For the secondary outcome of death from any cause, data were censored when a patient entered palliative care.

The statistical analysis began on December 1, 2021, when the administrative data linkages for follow-up outcomes first became available. However, our statistical analysis plan did not include adjustment for the type I error rate for two copri-

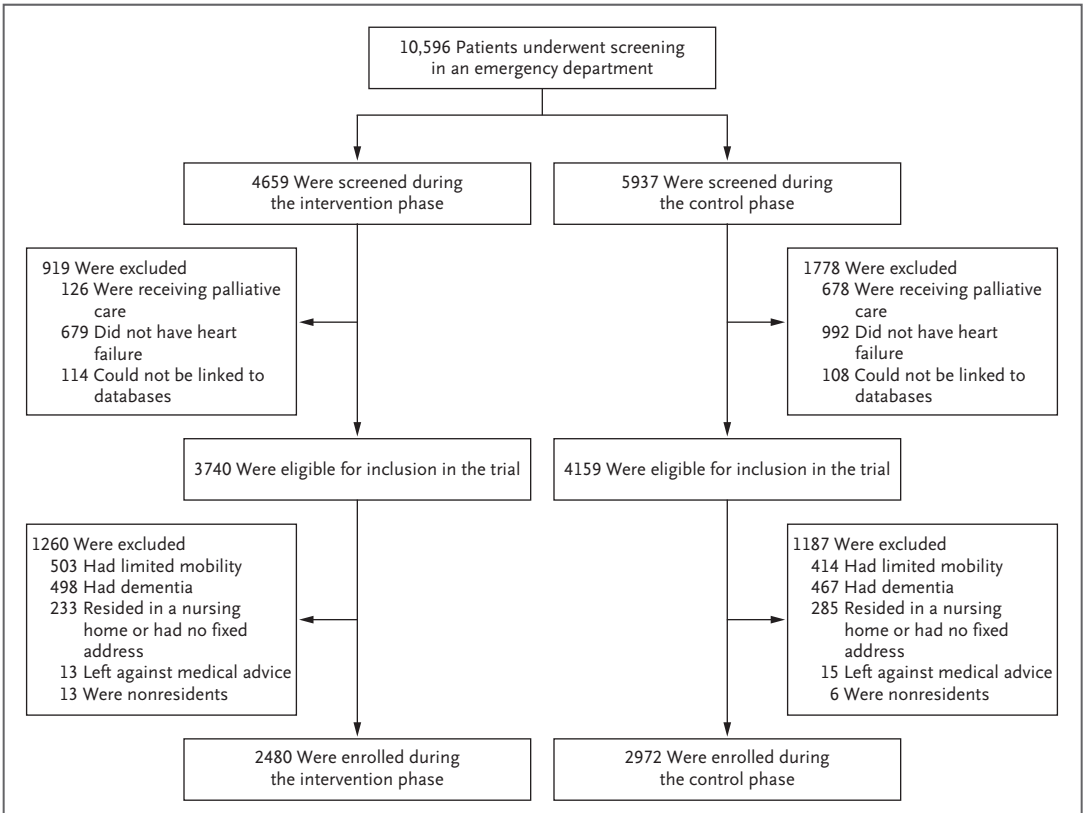

Figure 1. Patient Enrollment According to Hospital Phase.

mary outcomes and did not specify alpha allocation. Therefore, a P value is reported for the 30-day coprimary outcome only. The remainder of the data are presented as point estimates and 95% confidence intervals. A two-sided P value of less than 0.05 was considered to indicate significance. The widths of the 95% confidence intervals were not adjusted for multiple comparisons and should not be used to infer definitive effects of the intervention.

RESULTS

PATIENTS

Of the 10,596 patients who presented to the emergency department with acute heart failure, 7899 were eligible for inclusion in the trial. After the exclusion of those who had reasons that limited them from attending visits in the RAPID-HF clinic, 5452 patients were enrolled in the trial (2972 during the control phase and 2480 during the intervention phase) (Fig. 1). The patients who were enrolled during the two phases were well matched with respect to baseline characteristics (Table 1 and Table S12); there was a high percentage of patients who had a history of heart failure in both groups (Table S13). The trial population was representative of patients with heart failure in the general population; the distributions according to age, sex, and race or ethnic group were similar to those observed in population-based studies (Table S14).[5,23] No patients were no lost to follow-up.

PATIENT RISK GROUPS, EARLY DISCHARGE, AND OUTPATIENT CARE

During the control phase, hospitals did not have access to the EHMRG30-ST tool, and risk scores could not be determined by hospital staff. For this phase, risk scores could be calculated after completion of the trial, during the analysis stage, for 2919 of 2972 patients (98.2%). Of the 2919 patients, 531 (18.2%) had a low risk, 824 (28.2%) had an intermediate risk, and 1564 (53.6%) had a high risk. During the intervention phase, risk scores could be calculated with the

Table 1. Characteristics of the Patients at Baseline.*

Characteristic	Intervention (N = 2480)	Control (N = 2972)
Median age (IQR) — yr	78 (68–85)	78 (68–85)
Female sex — no. (%)	1125 (45.4)	1336 (45.0)
Hypertension — no. (%)	1810 (73.0)	2289 (77.0)
Diabetes — no. (%)	960 (38.7)	1227 (41.3)
Previous myocardial infarction — no. (%)	377 (15.2)	526 (17.7)
Chronic atrial fibrillation or flutter — no. (%)	952 (38.4)	1012 (34.1)
Stroke or transient ischemic attack — no. (%)	321 (12.9)	403 (13.6)
Severe mitral or aortic valvular heart disease — no. (%)	331 (13.3)	466 (15.7)
Cancer — no. (%)	128 (5.2)	113 (3.8)
Previous diagnosis of heart failure — no./total no. ≥40 yr of age (%)	1551/2447 (63.4)	1913/2928 (65.3)
Median no. of previous hospitalizations for heart failure since onset (IQR)	0 (0–0)	0 (0–1)
Presenting signs		
Median systolic blood pressure (IQR) — mm Hg	138 (121–158)	135 (116–155)
Median heart rate (IQR) — beats/min	85 (71–103)	88 (73–107)
Median oxygen saturation (IQR) — %	95 (92–97)	94 (89–96)
Medications before presentation — no. (%)		
Renin–angiotensin system inhibitor†	1293 (52.1)	1538 (51.7)
Beta-blocker	1538 (62.0)	1793 (60.3)
Mineralocorticoid-receptor inhibitor	263 (10.6)	331 (11.1)
Sodium–glucose cotransporter 2 inhibitor	69 (2.8)	38 (1.3)
Furosemide	1279 (51.6)	1614 (54.3)
Metolazone	53 (2.1)	58 (2.0)
Laboratory test results in emergency department		
Median eGFR (IQR) — ml/min/1.73 m^2	56.5 (38.6–76.5)	55.8 (37.1–76.1)
Median potassium concentration (IQR) — mEq/liter	4.0 (4.0–5.0)	4.0 (4.0–5.0)
Elevated troponin level — no./total no. (%)‡	879/2388 (37)	1152/2887 (40)
Left ventricular ejection fraction — no. (%)		
≤40%: Heart failure with reduced ejection fraction	684 (27.6)	818 (27.5)
41–49%: Heart failure with middle-range ejection fraction	231 (9.3)	291 (9.8)
≥50%: Heart failure with preserved ejection fraction	953 (38.4)	1039 (35.0)
Not assessed	612 (24.7)	824 (27.7)

* Percentages may not total 100 because of rounding. The term eGFR denotes estimated glomerular filtration rate, and IQR interquartile range.

† Renin–angiotensin system inhibitors include angiotensin-converting–enzyme inhibitors, angiotensin-receptor blockers, and sacubitril–valsartan.

‡ An elevated troponin level was defined as a level higher than the upper limit of the normal range used for the detection of myocardial injury or used for non–high-sensitivity assays or a level more than three times the 99th percentile used for high-sensitivity assays.

use of the EHMRG30-ST tool for 2442 of 2480 patients (98.5%). Of the 2442 patients, 575 (23.5%) had a low risk, 783 (32.1%) had an intermediate risk, and 1084 (44.4%) had a high risk.

Among high-risk patients, early discharge (i.e., discharge directly from the emergency department or discharge after a hospitalization of ≤3 days) occurred in 423 of 1564 patients (27.0%)

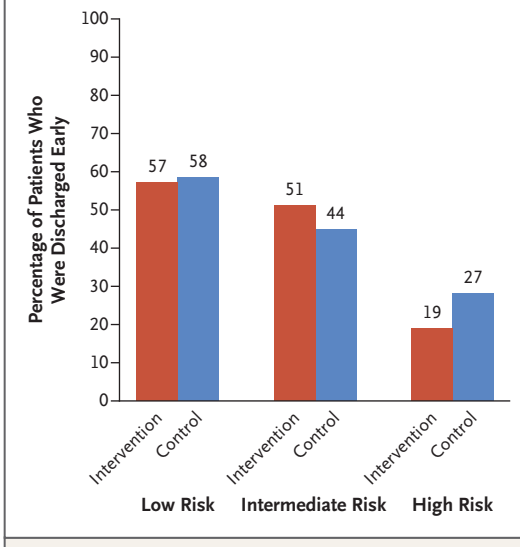

Figure 2. Early Discharge According to Risk Group.
Early discharge was defined as either discharge directly from the emergency department or discharge after a hospitalization of up to 3 days.

who were enrolled during the control phase and in 207 of 1084 patients (19.1%) who were enrolled during the intervention phase (Fig. 2 and Fig. S4). Among intermediate-risk patients, early discharge occurred in 364 of 824 patients (44.2%) and in 397 of 783 patients (50.7%) who were enrolled during the control phase and the intervention phase, respectively. Among low-risk patients, early discharge occurred in 309 of 531 patients (58.2%) and in 328 of 575 patients (57.0%) who were enrolled during the control phase and the intervention phase, respectively. Early discharge was most likely to occur on the first day after presentation, and trends for discharge directly from the emergency department were consistent with trends for early discharge (Fig. S5).

For low-risk patients who were discharged early, the median time to the first outpatient visit was 4 days (interquartile range, 2 to 7) among those enrolled during the intervention phase and 4 days (interquartile range, 3 to 8) among those enrolled during the control phase (adjusted hazard ratio, 1.10; 95% confidence interval [CI], 0.94 to 1.28). In addition, the median time to the first outpatient visit with either an internist or a cardiologist was 6 days (interquartile range, 3 to 12) among those enrolled during the intervention phase and 12 days (interquartile range, 5 to 29) among those enrolled during the control phase (adjusted hazard ratio, 1.38; 95% CI, 1.08 to 1.76).

For intermediate-risk patients who were discharged early, the median time to the first outpatient visit was 4 days (interquartile range, 2 to 7) among those enrolled during the intervention phase and 5 days (interquartile range, 3 to 9) among those enrolled during the control phase. The median time to the first outpatient visit with either an internist or a cardiologist was 7 days (interquartile range, 3 to 20) and 9 days (interquartile range, 4 to 27) among those enrolled during the intervention phase and the control phase, respectively.

For high-risk patients who were discharged early, the median time to the first outpatient visit was 5 days (interquartile range, 3 to 9) among those enrolled during the intervention phase and 5 days (interquartile range, 3 to 11) among those enrolled during the control phase. The median time to the first outpatient visit with either an internist or a cardiologist was 11 days (interquartile range, 4 to 27) and 13 days (interquartile range, 5 to 33) among those enrolled during the intervention phase and the control phase, respectively. Additional results regarding outpatient visits with stratification according to risk group are shown in Table S15.

OUTCOMES WITHIN 30 DAYS

Within 30 days, death from any cause or hospitalization for cardiovascular causes occurred in 301 patients (12.1%) who were enrolled during the intervention phase and in 430 patients (14.5%) who were enrolled during the control phase (adjusted hazard ratio, 0.88; 95% CI, 0.78 to 0.99; P=0.04). The risk of hospitalization for cardiovascular causes appeared to be lower during the intervention phase than during the control phase (adjusted hazard ratio, 0.85; 95% CI, 0.74 to 0.98), as did the risk of hospitalization for heart failure (adjusted hazard ratio, 0.81; 95% CI, 0.69 to 0.95). Results for other secondary outcomes within 30 days are shown in Table 2.

A post hoc analysis of primary-outcome events within 30 days with stratification according to risk group was performed. Death from any cause or hospitalization for cardiovascular causes occurred in 36 low-risk patients (6.3%) enrolled

Table 2. Primary and Secondary Outcomes within 30 Days.

Outcome	Intervention (N=2480)	Control (N=2972)	Adjusted Hazard Ratio (95% CI)	P Value
Primary outcome				
Composite of death from any cause or hospitalization for cardiovascular causes — no. (%)	301 (12.1)	430 (14.5)	0.88 (0.78–0.99)	0.04
Secondary outcomes				
Hospitalization for cardiovascular causes — no./total no. (%)	190/2343 (8.1)	294/2775 (10.6)	0.85 (0.74–0.98)	—
Hospitalization for heart failure — no./total no. (%)	142/2343 (6.1)	222/2775 (8.0)	0.81 (0.69–0.95)	—
Death from any cause — no. (%)	147 (5.9)	196 (6.6)	0.94 (0.74–1.19)	—
Composite of emergency department visit, death from any cause, or hospitalization for cardiovascular causes — no. (%)	687 (27.7)	851 (28.6)	0.97 (0.85–1.11)	—

during the intervention phase and in 36 low-risk patients (6.8%) enrolled during the control phase (hazard ratio, 0.88; 95% CI, 0.55 to 1.39); in 67 intermediate-risk patients (8.6%) enrolled during the intervention phase and in 100 intermediate-risk patients (12.1%) enrolled during the control phase (hazard ratio, 0.66; 95% CI, 0.43 to 1.01); and in 190 high-risk patients (17.5%) enrolled during the intervention phase and in 285 high-risk patients (18.2%) enrolled during the control phase (hazard ratio, 1.05; 95% CI, 0.91 to 1.21) (Table S17).

OUTCOMES WITHIN 20 MONTHS

Within 20 months, the cumulative incidence of death from any cause or hospitalization for cardiovascular causes was 54.4% (95% CI, 48.6 to 59.9) among patients who were enrolled during the intervention phase and 56.2% (95% CI, 54.2 to 58.1) among patients who were enrolled during the control phase (adjusted hazard ratio, 0.95; 95% CI, 0.92 to 0.99). The intervention appeared to be associated with lower risks of hospitalization for cardiovascular causes and hospitalization for heart failure (Table S16). The median follow-up time was 280 days (interquartile range, 82 to 520) among patients enrolled during the control phase and 144 days (interquartile range, 64 to 286) among patients enrolled during the intervention phase. Cumulative-incidence curves from adjusted and unadjusted analyses of early and extended outcomes are shown in Figure 3, and curves for secondary outcomes are shown in Figures S6, S7, and S8.

SERIOUS ADVERSE EVENTS

Among patients who were enrolled during the intervention phase, the risk of serious adverse events occurring before the first outpatient visit within 30 days after discharge did not appear to be higher than the risk among patients who were enrolled during the control phase. Specifically, no deaths or hospitalizations for any cause occurred in low- or intermediate-risk patients before the first outpatient visit within 7 days, and fewer than six events occurred within 30 days (Table S18).

DISCUSSION

In this trial of a strategy for patients with heart failure, the use of a validated point-of-care tool for risk stratification in the emergency department to support clinicians in making decisions about discharging or admitting patients, combined with the provision of standardized transitional care, led to a 12% lower risk of death from any cause or hospitalization for cardiovascular causes within 30 days after presentation than usual care. The intervention also led to a lower risk of death from any cause or hospitalization for cardiovascular causes within 20 months. The risks of hospitalization for cardiovascular causes and hospitalization for heart failure after the index presentation also appeared to be lower among patients who were enrolled during the intervention phase than among those who were enrolled during the control phase.

Not all patients who present to the emergency

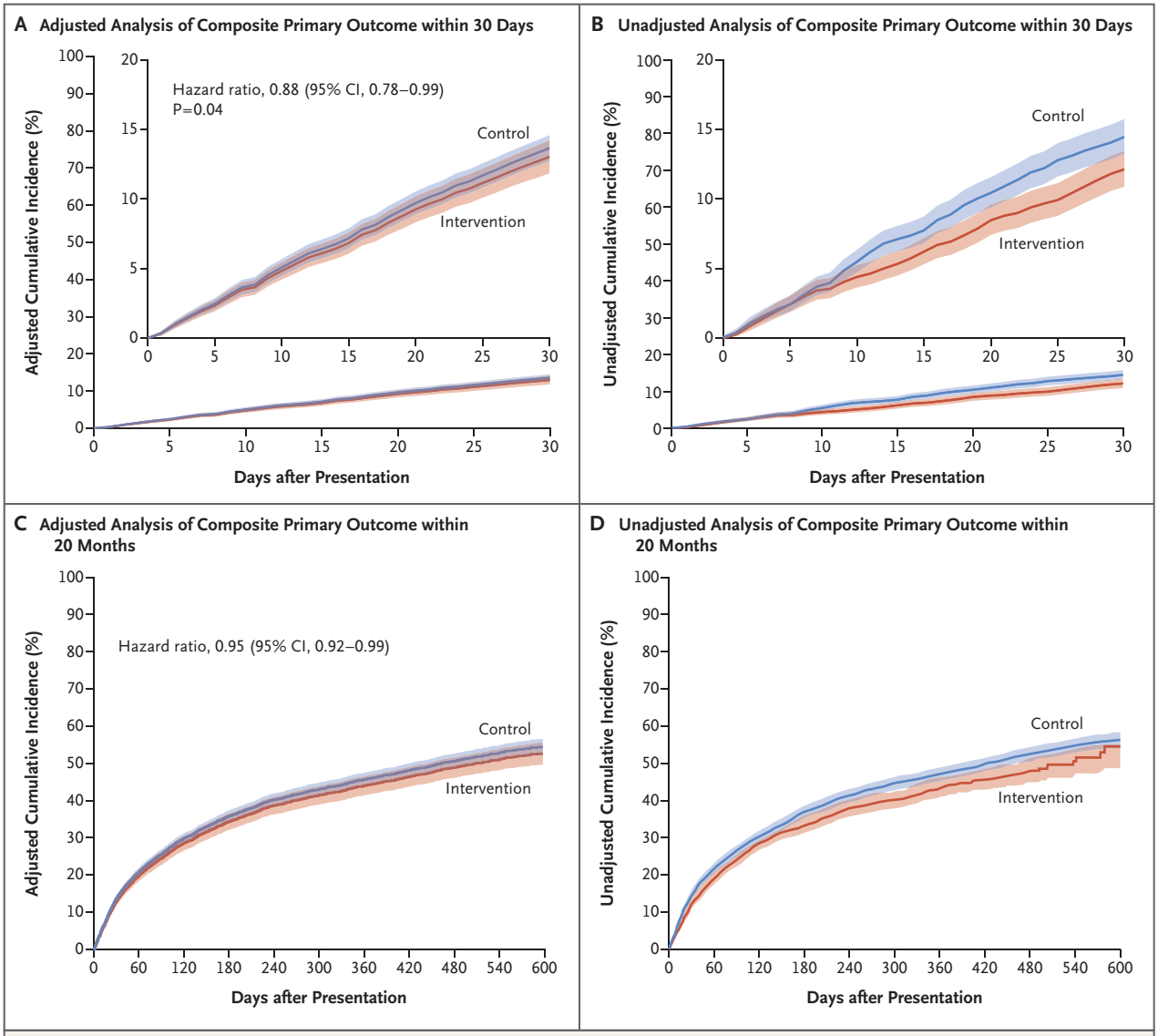

Figure 3. Cumulative Incidence of the Composite of Death from Any Cause or Hospitalization for Cardiovascular Causes.

The first coprimary outcome was a composite of death from any cause or hospitalization for cardiovascular causes within 30 days after presentation to the emergency department, and the second coprimary outcome was the composite outcome within 20 months after presentation. Cumulative-incidence curves from adjusted and unadjusted analyses of the first coprimary outcome (Panels A and B, respectively) and from adjusted and unadjusted analyses of the second coprimary outcome (Panels C and D, respectively) are shown. Shading indicates the 95% confidence interval. Insets show the same data on an enlarged y axis.

department with heart failure require hospitalization.[24] A barrier to the selection of patients for early hospital discharge is the inability to accurately predict the occurrence of adverse events on the basis of physician risk estimation alone.[25] The ability to prognosticate more accurately may enable physicians to make informed decisions about appropriate care settings, may enhance safety by reducing discharge of high-risk patients, and may improve efficiency by reducing admission of lower-risk patients.[7] In our trial, the strategy of risk assessment with a validated algorithm, combined with the provision of transitional care, was associated with a lower risk of hospitalization among patients with heart failure.

Transitional care for patients with acute heart failure has had varied degrees of success,[26-28] but it may be an important intervention nonetheless.

Feltner et al. reported that the provision of transitional care reduced the 30-day risk of readmission, whereas primary care visits and educational programs alone tended to increase the risk of hospitalization.[29] In the Patient-Centered Care Transitions in Heart Failure study, a peridischarge intervention that consisted of patient education, a structured hospital-discharge summary, a family-physician appointment, and home visits by a nurse did not reduce the risks of readmission for any cause, emergency department visits, or death.[30] The involvement of specialists[31] and the rapidity of outpatient follow-up[32] may be important, since readmissions can occur within the first few days after hospital discharge.[33]

Our intervention was complex and multipronged, with several potential mechanisms of benefit. Physicians tend to underestimate risk for those with the worst prognosis,[17] which could lead to inadvertent discharge of high-risk patients.[7] In addition, earlier follow-up may be advantageous, because readmissions occur frequently after shorter index hospital admissions.[19]

Our findings support the concept that not all patients who present to the emergency department with heart failure require hospitalization. If a patient is not assessed as having a high risk with the use of a broadly validated method, and if a structured outpatient clinic is available for rapid follow-up, then this lower-risk patient may be discharged directly from the emergency department or discharged early after hospital admission. Prospective testing before implementation is important, and pragmatic randomized trials represent an approach for this form of evaluation.[34,35] Policymakers may consider appropriate discharge with rapid follow-up to be a viable alternative to hospitalization in some situations.

This trial has some limitations. First, the trial design limited our ability to determine which aspects of the complex intervention had the greatest effect. For example, the RAPID-HF clinic was managed by a nurse and supervised by a cardiologist, so the effect that was attributable to care by a cardiac specialist could not be ascertained. Second, a health system–based trial of a complex intervention is subject to the "learning curve" of the health care team. Although acceleration of the learning process was made possible by a nurse navigator, benefits could be underestimated in the evaluation of early outcomes, because care processes become more efficient over time. Third, race or ethnic group was not known for more than half the participants in each group. Therefore, we cannot make any conclusions about the effect of race or ethnic group on outcomes. Finally, not all patients could be linked to data on follow-up outcomes, and the success of the linkage appeared to be marginally higher among patients who were enrolled during the control phase.

For patients with acute heart failure who presented to the emergency department, the systematic use of a point-of-care tool to support clinical decision making, coupled with rapid follow-up in an outpatient clinic, led to a lower risk of death from any cause or hospitalization for cardiovascular causes within 30 days after presentation than usual care. Implementation of this approach across health systems may provide a pathway for early and safe discharge from the hospital or emergency department and improved patient outcomes.

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APPENDIX

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