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Effect of a Hospital and Postdischarge Quality Improvement Intervention on Clinical Outcomes and Quality of Care for Patients With Heart Failure With Reduced Ejection Fraction

The CONNECT-HF Randomized Clinical Trial

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IMPORTANCE Adoption of guideline-directed medical therapy for patients with heart failure is variable. Interventions to improve guideline-directed medical therapy have failed to consistently achieve target metrics, and limited data exist to inform efforts to improve heart failure quality of care.

OBJECTIVE To evaluate the effect of a hospital and postdischarge quality improvement intervention compared with usual care on heart failure outcomes and care.

DESIGN, SETTING, AND PARTICIPANTS This cluster randomized clinical trial was conducted at 161 US hospitals and included 5647 patients (2675 intervention vs 2972 usual care) followed up after a hospital discharge for acute heart failure with reduced ejection fraction (HFrEF). The trial was performed from 2017 to 2020, and the date of final follow-up was August 31, 2020.

INTERVENTIONS Hospitals (n = 82) randomized to a hospital and postdischarge quality improvement intervention received regular education of clinicians by a trained group of heart failure and quality improvement experts and audit and feedback on heart failure process measures (eg, use of guideline-directed medical therapy for HFrEF) and outcomes. Hospitals (n = 79) randomized to usual care received access to a generalized heart failure education website.

MAIN OUTCOMES AND MEASURES The coprimary outcomes were a composite of first heart failure rehospitalization or all-cause mortality and change in an opportunity-based composite score for heart failure quality (percentage of recommendations followed).

RESULTS Among 5647 patients (mean age, 63 years; 33% women; 38% Black; 87% chronic heart failure; 49% recent heart failure hospitalization), vital status was known for 5636 (99.8%). Heart failure rehospitalization or all-cause mortality occurred in 38.6% in the intervention group vs 39.2% in usual care (adjusted hazard ratio, 0.92 [95% CI, 0.81 to 1.05). The baseline quality-of-care score was 42.1% vs 45.5%, respectively, and the change from baseline to follow-up was 2.3% vs −1.0% (difference, 3.3% [95% CI, −0.8% to 7.3%]), with no significant difference between the 2 groups in the odds of achieving a higher composite quality score at last follow-up (adjusted odds ratio, 1.06 [95% CI, 0.93 to 1.21]).

CONCLUSIONS AND RELEVANCE Among patients with HFrEF in hospitals randomized to a hospital and postdischarge quality improvement intervention vs usual care, there was no significant difference in time to first heart failure rehospitalization or death, or in change in a composite heart failure quality-of-care score.

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Supplemental content

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Heart failure with reduced ejection fraction (HFrEF) affects more than an estimated 3 million people in the US.[1] Despite the availability of multiple treatment options, outcomes remain suboptimal, with high rates of rehospitalization and death.[2] This is due, in part, to inadequate adoption of guideline-directed medical therapy.[3] Heart failure quality improvement efforts by hospitals and health systems are common, but limited data exist from multicenter, randomized controlled studies to inform current quality improvement efforts for hospitals and health systems attempting to improve care for patients discharged with acute HFrEF. Previous recommendations for improving evidence-based care include educational outreach to clinicians on how to implement guideline recommendations and audit and feedback of clinical performance, such as use of guideline-directed medical therapy.[4,5]

The objective of this cluster randomized trial was to test the effect of a hospital and postdischarge quality improvement intervention compared with usual care on heart failure outcomes and quality of care. The intervention specifically focused on education delivered by external experts and use of audit and feedback for heart failure process measures, such as use of guideline-directed medical therapy for HFrEF. Data on monthly process improvements at the hospital and patient level were provided to sites and were used by a trained group of heart failure and quality improvement experts in regular education sessions for clinicians. The primary hypothesis was that the intervention would improve clinical outcomes as measured by rates of heart failure rehospitalization or death and quality-of-care delivery over 12 months of follow-up compared with usual care.

Key Points

Question Can a hospital and postdischarge intervention focused on education on heart failure care as well as audit and feedback on care processes improve postdischarge outcomes and quality of care for patients with heart failure with reduced ejection fraction?

Findings In this cluster randomized trial that included 5647 patients and 161 hospitals, patients in hospitals randomized to the quality improvement intervention compared with usual care had a rate of rehospitalization or death of 38.6% vs 39.2% and change in quality-of-care scores of 2.3% vs −1.0%, respectively; neither comparison was statistically significant.

Meaning A hospital and postdischarge quality improvement intervention did not result in better clinical outcomes or measure of quality of care for patients with heart failure with reduced ejection fraction.

Methods

Details on design of the Care Optimization Through Patient and Hospital Engagement Clinical Trial for Heart Failure (CONNECT-HF) have been described.[6] The full study protocol and statistical analysis plan are available in Supplement 1. We conducted a cluster randomized trial in 161 hospitals in the US to evaluate the effect of the quality improvement intervention (eTable 1 in Supplement 2).

The intervention included site-level clinician education and quality improvement strategic planning that comprised a site-specific gap analysis and quality improvement action plan. Subsequent audit and feedback were provided to each site monthly, which included a report on processes and outcomes for achievement of guideline-based heart failure care. The quality improvement intervention was deployed at randomized intervention hospitals, and outcomes were assessed at the patient level following discharge to home after a hospitalization for acute HFrEF.

The trial was led by an independent academic steering committee and a patient-advisory panel. All participating hospitals obtained institutional review board approval. All patients were required to sign written informed consent prior to collection of any study data. The trial was coordinated and the data were analyzed by the Duke Clinical Research Institute.

Hospitals and Patients

Randomization occurred at the hospital level, with eligible hospitals treating a minimum of 50 patients with heart failure annually and having the capacity to perform a system-based quality improvement intervention. Hospitals enrolled adult patients with HFrEF (defined by symptomatic heart failure and left ventricular ejection fraction ≤40%) who were being discharged to home. Exclusion criteria included previous heart transplant or current/planned implantation of a left ventricular assist device, chronic use of dialysis, and a terminal illness other than HFrEF with a life expectancy less than 1 year. Data on patient race and ethnicity were ascertained to ensure adequate representation of all groups in the study and were self-reported based on fixed categories.

Randomization

The planned study design was to evaluate the effect of 2 quality improvement interventions: the hospitals- and postdischarge-level intervention previously described and a patient-level digital intervention of a mobile application. Originally, only patients with the capacity to use mobile applications on a smartphone were eligible for enrollment. Because of early concerns that this might limit the generalizability of the results, the patient eligibility criteria were broadened (protocol amended on February 5, 2018, to include those with or without a smartphone) and the patient-level digital study became an optional ancillary study for potentially eligible patients. These results will be published separately. Stratified randomization with permuted blocks was used to ensure that treatment allocations were balanced by baseline hospital size and 30-day rehospitalization rates. We used strata determined by combinations of baseline hospital size greater than 437 vs 437 or less and 30-day excess readmission rates of 1 or greater vs less than 1. The randomization schema was created by the study statistician using a computerized random number generator. After the decision was made to make the patient-level digital study optional, no change was made to the original randomization schema.

Quality Improvement Intervention

The intervention included implementation of site-based quality improvement initiatives targeting discharge, transition, and outpatient care delivery processes associated with guideline-directed medical therapy for patients with heart failure. The specific activities implemented at each site were designed in response to a site-based gap analysis and action planning exercise undertaken by the hospital clinical and quality improvement teams, with guidance and coaching from the CONNECT-HF Academy, a group of heart failure clinicians and quality improvement leaders who underwent specialized training for the study.[6] The intervention incorporated principles for implementation[4] using external experts to deliver education and using site-level audit and feedback to ensure ongoing engagement with the target metrics for improved quality, in this case national quality metrics for guideline-directed medical therapy.

The intervention was designed in accordance with the recommendations of the National Heart, Lung, and Blood Institute Implementation Science Working Group[5] and conducted using principles for replication and generalizability set forth by the Medical Research Council.[6] Hospitals randomized to usual care received access to a generalized heart failure education website.

Outcomes

The 2 coprimary outcomes were a composite of first heart failure rehospitalization or all-cause death and change in an opportunity-based composite score for heart failure quality. The composite quality score evaluated the guideline-based recommendations for quality of care provided at the time of hospital discharge and during outpatient follow-up (components of the score are reported in eTable 2 in Supplement 2). The score was the percentage of total opportunities that were successfully accomplished. If patients were not eligible for a quality metric (eg, documented allergy to a class of heart failure medications), they were not considered eligible for a quality metric and were excluded from the composite score. The denominator reflected only those metrics for which the patient was eligible.

Secondary outcomes included total number of heart failure rehospitalizations, all-cause death, and an opportunity-based quality score at the time of heart failure discharge. Clinical events were determined by blinded physician reviewers.

Sample Size

An overall sample size of 160 hospitals was planned, with a mean cluster size of 40 patients (approximately 6240 total patients), with the following assumptions: a 30% event rate to detect a 15% relative reduction in the intervention group on time to first heart failure rehospitalization or death, an intracluster correlation coefficient of 0.01, a coefficient of variation of cluster size of 0.65, and 85% power.[6] The study was powered to detect a 15% relative reduction in heart failure rehospitalization or death. This threshold was prospectively determined by the steering committee to be clinically meaningful in that it could lead to a change in practice and that such a change was consistent with previous studies on heart failure transitional care.[7] The overall type I error of .05 was split to .04 allocated for the clinical end point (heart failure rehospitalization or death) and .01 for the quality metric end point. For the composite quality score outcome, the planned sample size had greater than 90% power to detect a difference as small as 10% absolute improvement in the intervention group, assuming a 50% adherence rate over 12 months with usual care and an absolute improvement of 10% in the intervention group.

Statistical Analysis

Baseline patient and hospital characteristics were summarized as the mean (SD) for continuous variables and as counts (percentages) for categorical variables. Comparisons in baseline patient and hospital characteristics between the intervention and usual care groups were conducted using the Wilcoxon rank-sum test for continuous variables and χ^2 or Fisher exact test for categorical variables. Baseline variables for risk adjustment were imputed to modes for categorical variables and medians for continuous variables. Extremely large laboratory values were truncated to the 99th percentile for regression models.

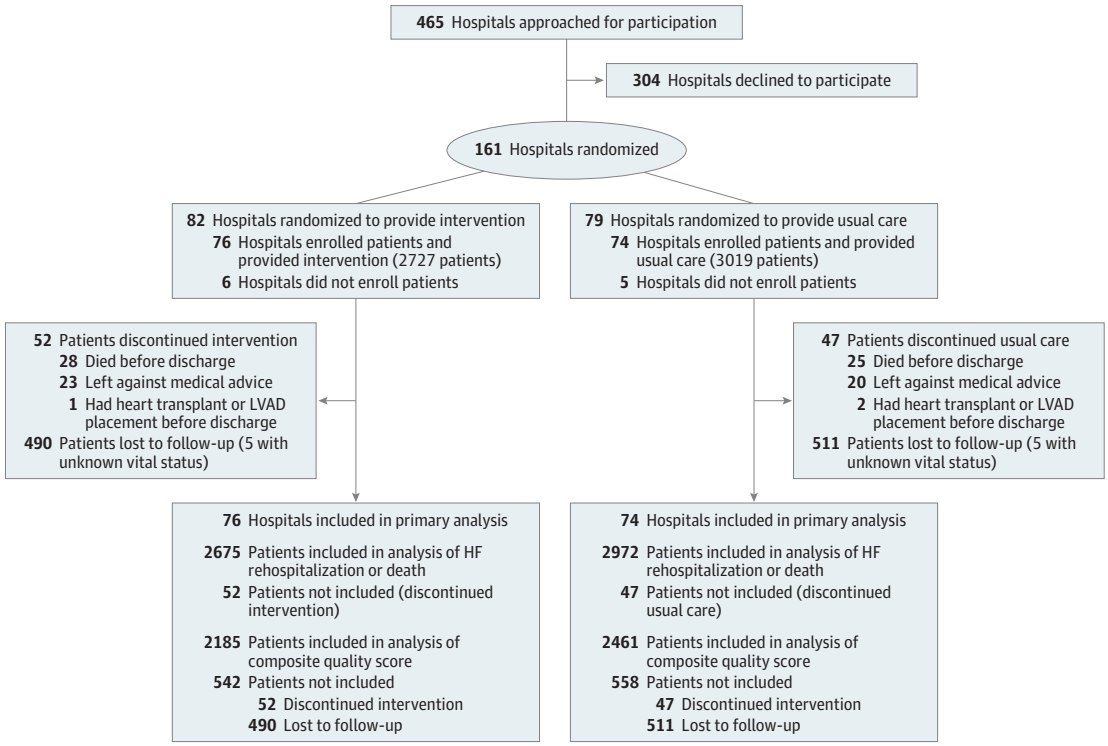
Primary analysis excluded patients who died, withdrew, underwent heart transplant or left ventricular assist device procedures, or left against medical advice before discharge from the index hospitalization. Follow-up time was censored on the minimum date of study withdrawal, last known alive, heart transplant, left ventricular assist device procedure, or last planned study visit after discharge. The opportunity-based composite score outcome was measured at the patient's last follow-up prior to censoring, if censored, and was restricted to patients with at least 1 postdischarge study visit. Patients missing quality metric data at the last follow-up had last observation carried forward for each eligible quality metric.

Estimates of the event rates by groups were calculated using Kaplan-Meier cumulative risk.[8] The primary analysis was conducted using a Cox proportional hazards model with shared frailty to account for clustering effect, adjusted for prespecified baseline factors (eTable 3 in Supplement 2).[9] We assessed the proportionality assumption graphically by plotting log[-log(survival)] vs log of time and tested by including a time-dependent covariate for intervention by log of time in the model; the assumptions were not violated.

Comparisons between the intervention and usual care groups for the coprimary outcome, the composite quality score, were calculated using an adjusted mixed-effects logistic regression model, treating each quality metric as an opportunity within the overall measure. Each patient was included in the model up to 6 times, depending on the number of eligible quality metrics. Clustering effect within a hospital was accounted for by including hospital as a random effect, and correlation between repeated opportunities within the same participant was modeled by a compound-symmetry covariance structure.[10,11] The composite quality score outcome was adjusted for the same prespecified baseline factors as the clinical outcome and also adjusted for baseline quality metrics.

Categorical variables were included as indicator variables. Continuous variables were assessed for linearity, and

Figure 1. Site and Patient Recruitment, Randomization, and Follow-up in the CONNECT-HF Cluster Randomized Trial



Randomization occurred at the hospital level, and the effect of the intervention was measured in consented patients. AMA indicates against medical advice; HF; heart failure; LVAD, left ventricular assist device.

cubic splines were used when linearity assumption was violated. Cluster heterogeneity was quantified using intracluster correlation coefficients. The primary quality metric outcome was expressed as the adjusted odds ratio (OR) of achieving a higher composite quality score at last follow-up, with an OR score greater than 1 indicating greater likelihood of a higher score.

Prespecified subgroups (age [≥65 years vs <65 years], sex, race, history diabetes, chronic kidney disease, atrial fibrillation, new-onset heart failure, and left ventricular ejection fraction [≥25% vs <25%]) were analyzed for both primary end points and presented with an interaction *P* value.

The secondary outcome for total heart failure rehospitalizations that included first and recurrent postdischarge hospitalizations for heart failure was analyzed using the Andersen-Gill model to estimate effect (hazard ratio [HR] with 95% CI) of the intervention, adjusted for key baseline variables with robust standard errors to account for correlated events within patients, censored for death.[12]

All statistical analyses were conducted using SAS version 9.4 (SAS Institute Inc) or R (R CORE Team, 2019) software. A 2-sided $P \leq .04$ was considered statistically significant for the clinical end point (heart failure rehospitalization or death) and $P \leq .01$ for the quality metric end point; a 2-sided $P \leq .05$ was used for all other outcomes. Because of the potential for type I error due to multiple comparisons, findings for analyses of secondary end points should be interpreted as exploratory.

Results

Baseline Characteristics of Patients and Hospitals

A total of 161 hospitals were randomized to the intervention (82 hospitals) or usual care (79 hospitals); from March 26, 2017, to May 22, 2020, 5746 patients were enrolled (2727 in the intervention group, 3019 in the usual care group) (**Figure 1**). A total of 99 patients were excluded from the clinical outcome analyses because they had events prior to hospital discharge. A total of 5647 patients were included in the analysis of the primary clinical outcome, and 4646 were included in the analysis of the primary composite quality score outcome (Figure 1). At the end of the study, vital status was known for all but 5 patients in the intervention group and 6 patients in the usual care group. Hospital characteristics were well balanced between groups (**Table 1**).

Baseline patient characteristics (Table 1) indicated a diverse population with a high burden of comorbid conditions. For variables included as covariates (eTable 3 in Supplement 2), absolute standardized differences were calculated. All covariates had an absolute standardized difference less than 10% except for calendar time (months) at discharge from trial start; for that variable, the absolute standardized difference was 14%.

The study was funded by an investigator-initiated grant from Novartis and was designed and contracted to finish by December 31, 2020. Owing to the COVID-19 pandemic, enrollment slowed in early 2020.[13] An extension of the study grant

Table 1. Baseline Patient and Hospital Characteristics

Characteristic	No. (%) Intervention (n = 2675)	No. (%) Usual care (n = 2972)
Patient		
Age, mean (SD), y	62.3 (13.8)	62.9 (13.4)
Sex		
Men	1797 (67.2)	1968 (66.2)
Women	878 (32.8)	1004 (33.8)
Race[a]		
White	1496 (55.9)	1672 (56.3)
Black	959 (35.9)	1204 (40.5)
Asian	75 (2.8)	19 (0.6)
Other	174 (6.5)	68 (2.3)
Hispanic or Latino ethnicity	117 (4.4)	109 (3.7)
Medical history		
HF hospitalization within 12 mo	1282 (53.3)	1505 (55.5)
Diabetes	1166 (43.6)	1412 (47.5)
Atrial fibrillation or flutter	1098 (41.1)	1273 (42.8)
Chronic kidney disease	369 (13.8)	393 (13.2)
New-onset heart failure	350 (13.1)	394 (13.3)
Heart rate, mean (SD), /min	91.8 (21.2)	91.8 (20.8)
Systolic blood pressure, mean (SD), mm Hg	134.4 (27.1)	135.6 (27.6)
BMI, mean (SD)[b]	32.9 (9.3)	32.9 (9.4)
Serum creatinine, mean (SD), mg/dL	1.47 (0.8)	1.45 (0.7)
LVEF <25%	1615 (60.4)	1682 (56.6)
Treatments before hospitalization		
Evidence-based β-blocker	1934 (73.7)	2158 (74.4)
ACEI/ARB/ARNI	1434 (58.5)	1646 (59.3)
ICD or CRT	853 (31.9)	980 (33.0)
Aldosterone antagonist	589 (22.8)	697 (24.1)
Anticoagulation	543 (20.5)	614 (20.7)
Composite HF quality-of-care score, successes/opportunities[c]	4443/10 549 (42.1)	5468/12 017 (45.5)
Hospital		
No.	82	79
Hospital size, No. of beds		
Mean (SD)[d]	431 (271)	454 (261)
Median (IQR)	388 (273-535)	380 (267-587)
Urban setting	78 (95.1)	75 (94.9)
Teaching hospital	16 (19.5)	19 (24.1)
Adult cardiology services	70 (94.6)	75 (100.0)
Interventional cardiology services	72 (97.4)	73 (97.3)
Cardiac surgery	59 (79.0)	68 (90.7)
GWTG-HF participation	26 (31.7)	27 (34.2)
30-d HF readmission rate, ERR ≥1[d]	37 (45.1)	35 (44.3)

Abbreviations: ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin-receptor blocker; ARNI, angiotensin receptor neprilysin inhibitor; BMI, body mass index; CRT, cardiac resynchronization therapy; ERR, excess readmission ratio; GWTG-HF, Get With The Guidelines—Heart Failure; HF, heart failure; ICD, implantable cardioverter-defibrillator; IQR, interquartile range; LVEF, left ventricular ejection fraction.

SI conversion factor: To convert serum creatinine values to µmol/L, multiply by 88.4.

[a] For race, patients may have selected more than 1 category. "Other" was a category on the case report form and indicated American Indian/Alaskan Native, Native Hawaiian/Pacific Islander, and Other.

[b] Calculated as weight in kilograms divided by height in meters squared.

[c] The composite quality score evaluated the guideline-based recommendations for quality of care provided at the time of hospital discharge and during outpatient follow-up. The score was the percentage of total opportunities successfully accomplished. Components of the score are shown in eTable 2 in the Supplement.

[d] Stratified randomization was used to ensure that treatment allocations were balanced by 2 hospital variables, baseline hospital size as defined by number of beds and 30-day rehospitalization rates as reported the Centers for Medicare & Medicaid Services excess readmission ratio of predicted-to-expected 30-day heart failure rehospitalizations.

was not possible. On May 5, 2020, enrollment data were reviewed at a steering committee meeting, and the decision was made to stop enrollment on May 22, 2020, with last follow-up visit on August 31, 2020. The steering committee remained blinded to the study results during this process.

Outcomes

For the primary clinical outcome, there were 2061 events, including 729 deaths. Time to first heart failure rehospitalization, deaths, or both in the intervention group (616 and 350, respectively; combined rate, 38.6%) were similar compared with the usual care group (716 and 379, respectively; rate, 39.2%; unadjusted HR of intervention vs control, 0.97 [95% CI, 0.84-1.12]; adjusted HR, 0.92 [95% CI, 0.81-1.05]) (**Table 2**, **Figure 2**).

For the baseline primary composite quality score, there were 4443 successful quality-of-care metrics among 10 549 opportunities (42.1%) in the intervention group and 5468

Table 2. Primary and Secondary Outcomes

Outcome	Intervention at follow-up	Usual care at follow-up	Absolute difference	Unadjusted ratio measure, HR (95% CI)	*P* value	Adjusted ratio measure, HR (95% CI)[a]	*P* value
Primary[b]							
HF rehospitalization or death, Kaplan-Meier rate (95% CI)	38.6 (36.7-40.6)	39.2 (37.4-41.1)	−0.6	0.97 (0.84-1.12)	.71	0.92 (0.81-1.05)	.21
HF quality of care composite score, successes/opportunities (%)[c,d]	4672/10 549 (44.3)	5363/12 017 (44.6)	−0.3	OR, 1.06 (0.94-1.20)	.31	OR, 1.06 (0.93-1.21)	.35
Secondary							
Clinical outcomes							
Total HF rehospitalizations, No. of events	1127	1326	−199	0.93 (0.82-1.06)	.29	0.87 (0.77-0.98)	.03
All-cause death, Kaplan-Meier rate (95% CI)	19.7 (18.1-21.2)	20.5 (19.0-22.1)	−0.8	0.94 (0.81-1.10)	.44	0.93 (0.81-1.06)	.28
HF discharge quality of care composite score, successes/opportunities (%)[d]	8815/11 214 (78.6)	9709/12 477 (77.8)	0.8	OR, 1.11 (0.89-1.38)	.36	OR, 1.14 (0.90-1.45)	.28

Abbreviations: HF, heart failure; HR, hazard ratio; OR, odds ratio.

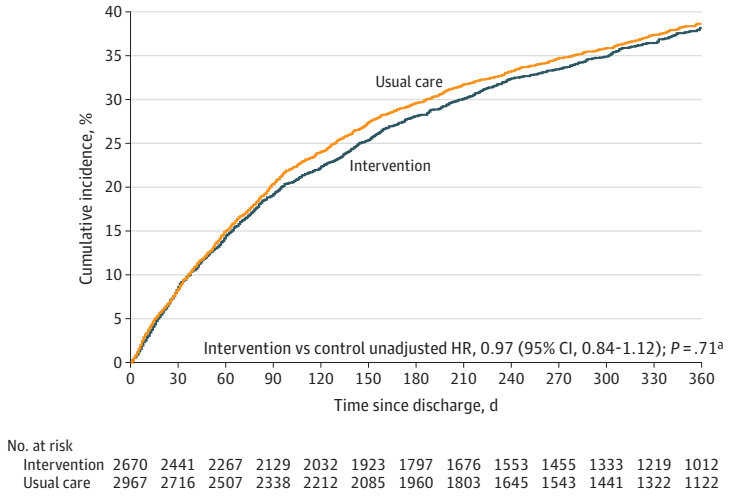
[a] Adjusted for site pretrial 30-day rehospitalization rates, geographic region, and hospital size as well as patient age, sex, race, diabetes, atrial fibrillation or flutter, chronic obstructive pulmonary disease, cerebrovascular accident/transient ischemic attack, chronic kidney disease, left ventricular ejection fraction, systolic blood pressure, discharge creatinine level, calendar time (months) at discharge from trial start, HF history vs new diagnosis, ischemic etiology, and 2 or more HF admissions in previous 12 months.

[b] Type I error rate (α) of .05 was split between 2 coprimary end points (.04 for the clinical end point and .01 for the quality-of-care end point).

[c] Also adjusted for baseline composite score. Baseline composite scores are reported in Table 1.

[d] The HF quality of care composite score evaluated the guideline-based recommendations for quality of care provided at the time of hospital discharge and during outpatient follow-up. The HF discharge quality of care composite score only evaluated the quality of care at hospital discharge.

Figure 2. Survival Curves for All-Cause Mortality or Heart Failure Rehospitalizations



Cumulative incidence of heart failure rehospitalization or death by study group. The median observation time was 299 days (range, 128-365) in the intervention group and 287 (range, 116-365) in the usual care group. HR indicates hazard ratio.

[a] *P* value for the comparison was derived from an unadjusted Cox proportional hazards model with shared frailty to account for clustering effect.

successful quality-of-care metrics among 12 017 opportunities (45.5%) in the usual care group (Table 2 and **Figure 3**; eTable 2 in Supplement 2). This improved to 44.3% in the intervention group and decreased to 44.6% in the usual care group over time. Neither group showed a significant change in the primary composite quality score, with a change from baseline to follow-up of 2.3% in the intervention group vs −1.0% in the usual care group (a between-group difference of 3.3 [95% CI, −0.8 to 7.3]). Similarly, there was no significant difference between the 2 groups in the odds of achieving a higher opportunity-based heart failure quality score at last follow-up (unadjusted OR, 1.06 [95% CI, 0.94-1.20]; adjusted OR, 1.06 [95% CI, 0.93-1.21]). Both primary outcomes were consistent across prespecified subgroups (eFigures 1 and 2 in Supplement 2).

The frequency of total heart failure rehospitalizations was 1127 in the intervention group and 1326 in the usual care group (unadjusted HR, 0.93 [95% CI, 0.82-1.06]; adjusted HR, 0.87 [95% CI, 0.77-0.99]) (Table 2). The all-cause death rate was similar in both groups (unadjusted HR, 0.94 [95% CI, 0.81-1.10]; adjusted HR, 0.93 [95% CI, 0.81-1.06]). The opportunity-based composite and individual quality metrics at the time of heart failure discharge were also similar in both groups (Table 2).

Adverse Events

The interventions recommended in the trial included approved medications and devices with well-described safety profiles. No additional solicited safety data capture was performed. Any serious or significant unexpected drug-related events were reported directly to the US Food and Drug Administration per usual clinical practices at each site.

Discussion

In this cluster randomized trial of hospitals treating patients after a hospitalization for HFrEF, a hospital and postdischarge quality improvement intervention that focused on clinician education and audit and feedback of heart failure quality of care did not reduce the composite of heart failure rehospitalization or all-cause death, nor did it improve a heart failure composite quality score compared with usual care. There was no significant difference between the 2 groups for most of the prespecified secondary outcomes, although there were fewer total heart failure hospitalizations in the intervention group after adjustment for differences in baseline characteristics.

Findings in this study demonstrate the magnitude of ongoing challenges facing hospitals and clinicians attempting to improve care for patients with heart failure. In this study, strategies of education and audit and feedback were implemented according to evidence-based strategies shown to be effective for improving both processes of care and clinical outcomes in other areas of medicine, including cardiovascular disease.[4] Within hospitals, quality improvement activities were also aligned with and incorporated into existing quality improvement programs such as Get With The Guidelines–HF and the PINNACLE Registry.[14,15] Because of public attention to heart failure outcomes, many institutions have ongoing quality-of-care efforts. The present study was designed to augment those efforts, with 72% of hospitals having a preexisting quality improvement team focused on heart failure and 50% of hospitals participating in a national heart failure quality improvement program. While the substantial rates of preexisting quality improvement participation might help explain the neutral results of the current study, guideline-directed medical therapy use rates remained insufficient, with less than 50% of the most effective treatments being applied to patients, even when excluding situations in which patients were not eligible.

In previous studies, participating hospitals frequently used observational designs and found associated improvement in quality of care focused at the point of discharge. For example, hospitals participating in programs such as Get With The Guidelines–HF demonstrated better rates of process of care over time and when compared with nonparticipating

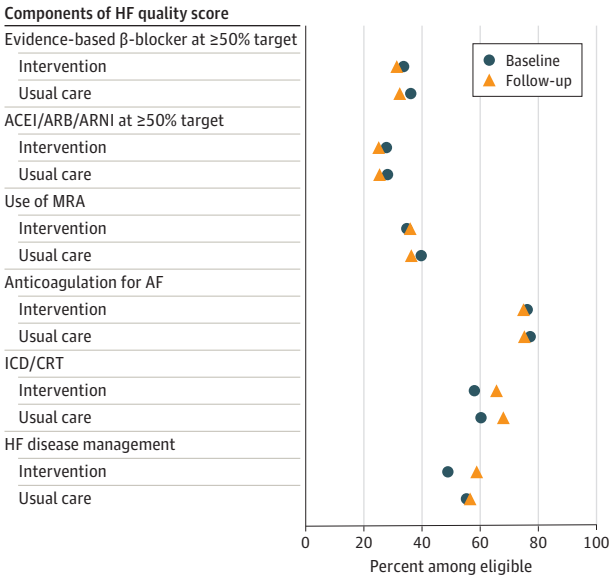
hospitals.[14,16] However, more intensive education and feedback has not always led to improved processes of care.[17] A possible implication of these previous studies in the context of the data presented herein is that systems may improve initially at the outset of a quality-of-care program but experience a ceiling effect. To extend improvements in care and outcomes, especially beyond hospital discharge, more resources or new approaches will be needed than those currently used in existing programs or local initiatives. This will be critically important with care models that rely on remote or decentralized care of heart failure, such as value-based care models.[18]

The current results are consistent with those from other studies that identify low use of guideline-directed medical therapy for HFrEF at target doses recommended in the heart failure guidelines.[19] In the Change the Management of Patients With Heart Failure (CHAMP-HF) registry, only 13%, 20%, and 25% of eligible patients were treated with target doses of angiotensin-converting enzyme inhibitors/angiotensin receptor blockers/angiotensin receptor neprilysin inhibitors, evidence-based β-blockers, or a mineralcorticoid receptor antagonist, respectively, and less than 1% were simultaneously treated with target doses of all 3 classes of medications over 12 months of follow-up.[3] In the current study, a modified measure was applied regarding use of renin-angiotensin-aldosterone system inhibitors and evidence-based β-blockers, requiring at least 50% of target dose to fulfill the quality metric, and rates of use of these medications at this threshold were again very low. There were also very low rates of sodium-glucose cotransporter-2 inhibitors, but these were not widely used for patients with type 2 diabetes and were only recently approved for use in patients with HFrEF and without type 2 diabetes.[20,21]

In addition, findings from this study underscore the challenges facing acute care facilities such as hospitals in implementing recommendations for care that require long-term, ongoing work across many clinicians in ambulatory care settings. Because clinicians who enrolled patients were often not the ones providing patient follow-up after discharge, the hospital-based study team had limited ability to influence postdischarge care. In an attempt to bridge this fragmentation in care, simple tips for electronic health record-based communication and outreach were designed and delivered monthly to sites, but these quality improvement initiatives were not effective. A similar finding was observed in the Patient-Centered Care Transitions in Heart Failure (PACT-HF) trial, designed to test the effectiveness of a group of heart failure transitional care services that were based on previous research and guideline recommendations.[22]

Taken together, these studies suggest that although hospitals are a common target for heart failure quality improvement initiatives, new approaches should be considered for improving guideline-directed medical therapy after hospital discharge, including use of emerging technology to engage patients and caregivers.[23,24] For example, in the Electronically Delivered, Patient-Activation Tool for Intensification of Medications for Chronic HFrEF (EPIC-HF) study, researchers suggested that a patient activation tool consisting of a 3-minute video with a 1-page medication checklist delivered electronically before a cardiology clinic visit improved clinician intensification of guideline-directed medical therapy.[23]

Figure 3. Change in Individual Components of the Heart Failure Process of Care Score Over Time



Change in components of the heart failure (HF) quality score. The score was based on guideline-based recommendations for quality of care provided at the time of hospital discharge and during outpatient follow-up and consisted of the following: (1) use of evidence-based β-blockers at 50% or greater of the target dose; (2) use of angiotensin-converting enzyme (ACE) inhibitor/angiotensin receptor blocker (ARB)/angiotensin receptor neprilysin inhibitor (ARNI) at 50% or greater of the target dose; (3) use of a mineralcorticoid receptor antagonist (MRA) at any dose; (4) use of anticoagulation for patients with atrial fibrillation (AF); (5) use of an implantable cardioverter-defibrillator (ICD) or cardiac resynchronization therapy (CRT); and (6) attendance at a multidisciplinary HF disease management program, a cardiac rehabilitation program, or HF group educational classes.

Limitations

This study has several limitations. First, the trial included only hospitals with the capacity to perform a system-based quality improvement program, and the results may not be generalizable to hospitals and health systems looking to initiate a heart failure quality improvement program.

Second, the hospitals in this study included both integrated and nonintegrated care delivery systems. The effect of the intervention may be different in health systems with integrated inpatient and outpatient care teams, such as those in accountable care organizations or single-payer systems.

Third, because informed consent was necessary to follow up patients after hospital discharge, the effect of the intervention was measured only in consented patients, a relatively small proportion of the patients treated for acute HFrEF at the participating hospitals during the study period. These hospital and patient selection elements likely provided a population with better care and outcome than an unselected population, making the gaps in care even larger than what this study observed.

Fourth, due to COVID-19, the patient enrollment was lower than planned. The study was planned assuming a minimal detectable relative reduction of 15% in heart failure rehospitalization or death as clinically meaningful, but this effect size was included in the confidence interval for the null primary outcome; therefore, the study may have been underpowered to detect a statistically significant but clinically important difference in this outcome.

Conclusions

Among patients with HFrEF in hospitals randomized to a hospital and postdischarge quality improvement intervention vs usual care, there was no significant difference in time to first heart failure rehospitalization or death, or in change in a composite heart failure quality-of-care score.

ARTICLE INFORMATION

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