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Post-Discharge Noninvasive Telemonitoring and Nurse Telephone Coaching Improve Outcomes in Heart Failure Patients with High Burden of Comorbidity

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Abstract

Background: Noninvasive telemonitoring and nurse telephone coaching (NTM-NTC) is a promising post-discharge strategy in heart failure (HF). Comorbid conditions and disease burden influence health outcomes in HF, but how comorbidity burden modulates the effectiveness of NTM-NTC is unknown. This study aims to identify HF patients who may benefit from post-discharge NTM-NTC based on their burden of comorbidity.

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Declaration of Competing Interest

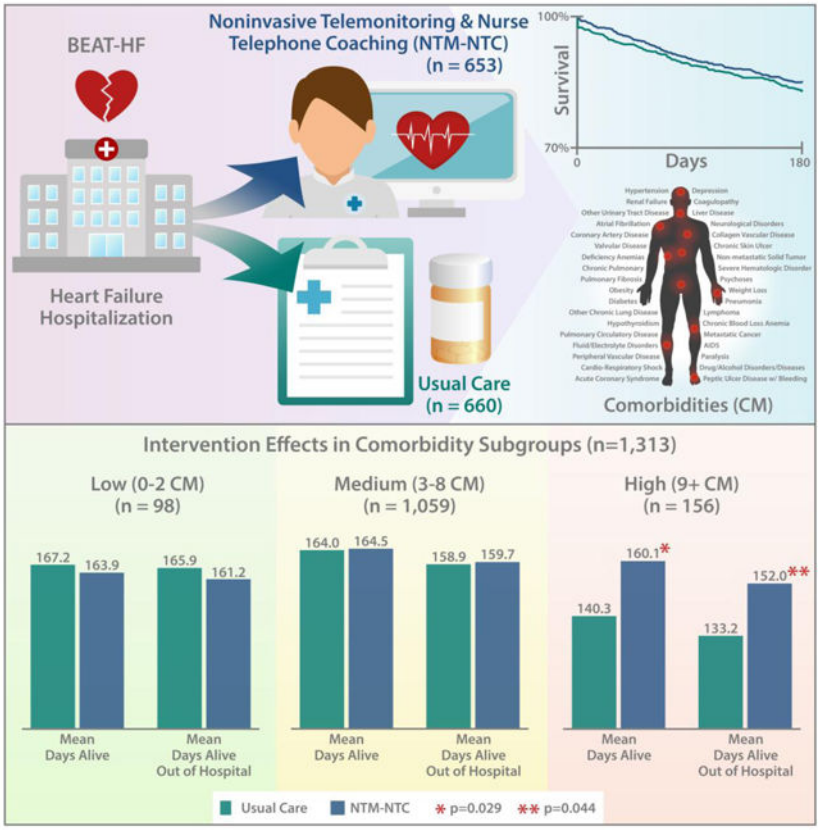
The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Methods: In the Better Effectiveness After Transition - Heart Failure trial, patients hospitalized for acute decompensated HF were randomized to post-discharge NTM-NTC or usual care. In this secondary analysis of 1,313 patients with complete data, comorbidity burden was assessed by scoring complication/coexisting diagnoses from index admissions. Clinical outcomes included 30-day and 180-day readmissions, mortality, days alive, and combined days alive and out of the hospital.

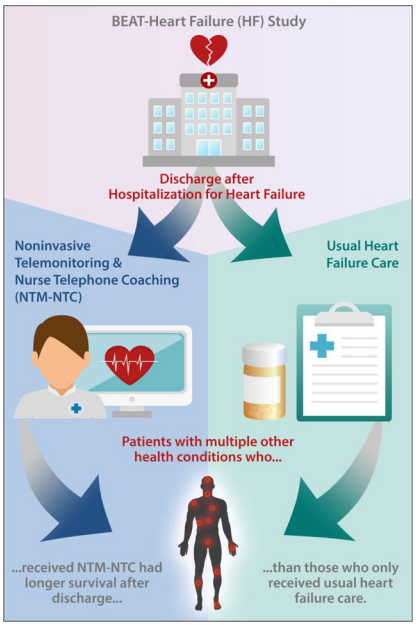
Results: Patients had a mean of 5.7 comorbidities and were stratified into low (0–2), moderate (3–8), and high comorbidity (9+) subgroups. Increased comorbidity burden was associated with worse outcomes. NTM-NTC was not associated with readmission rates in any comorbidity subgroup. Among high comorbidity patients, NTM-NTC was associated with significantly lower mortality at 30 days (hazard ratio (HR): 0.25; 95% confidence interval (CI): 0.07–0.90) and 180 days (HR: 0.51; 95% CI: 0.27–0.98), as well as more days alive (160.1 vs 140.3, p=0.029) and days alive out of the hospital (152.0 vs 133.2; p=0.044) compared to usual care.

Conclusions: Post-discharge NTM-NTC improved survival among HF patients with high comorbidity burden. Comorbidity burden may be useful for identifying patients likely to benefit from this management strategy.

Graphical Abstract



Graphical Abstract



Lay Summary

- Post-discharge telemonitoring and nurse telephone coaching can help manage care after being hospitalized with heart failure
- Our study looked at the benefits of this approach in different types of patients
- This approach was most likely to improve survival in patients who also had multiple other health problems

Post-discharge telemonitoring and nurse telephone coaching is a specialized approach to help patients with heart failure manage their health care after they return home from the hospital. It allows health care providers to remotely monitor blood pressure, heart rate, and other vital signs and symptoms. It also allows patients to receive regular virtual check-ins and guidance from a nurse without having to leave home. Our study found that patients who have heart failure and have multiple other health problems may be most likely to benefit from this approach in terms of improving survival and staying out of the hospital.

Proposed Social Media Text

Secondary analysis of a randomized controlled trial of noninvasive telemedicine post-discharge care suggests that a subgroup of heart failure patients with high burden of co-existing comorbidity may benefit with lower risk of mortality at 30- and 180-days after hospital discharge

Keywords

heart failure; noninvasive telemonitoring; nurse telephone coaching; burden of comorbidity

Introduction

Heart failure (HF) affected 6.2 million American adults from 2013–2016, and the prevalence continues to rise with the aging population.[1] Fifteen to 20% of HF hospitalizations will require readmission within 30 days, making HF the condition most likely to require readmission and contributing significantly to healthcare costs in the United States.[2, 3] Additionally, 55% of Medicare patients with HF have 5 or more other chronic conditions,[4] which significantly complicates medical care and contributes to increased morbidity and mortality.[5–7] Patients with 30-day readmissions have higher comorbidity burden than those not readmitted and are often readmitted for non-cardiac reasons.[2] Increased care burden in this population requires careful post-hospitalization management to optimize medication regimens and manage comorbidities. The identification of benefit/risk-based subgroups may allow for more efficient resource allocation and patient assignment in the post-discharge care of patients with HF. Noninvasive telemonitoring (NTM) incorporates objective data collection via devices such as scales or blood pressure - heart rate monitors into telephone-based care transition models. Other telemonitoring programs may collect subjective data only or data from invasive monitoring devices such as pulmonary artery pressure monitors or pacemakers/defibrillators.[8] Individual trials of NTM in HF patients have shown mixed results for HF-associated readmissions and all-cause mortality.[9–14] The analysis of the data in the original Better Effectiveness After Transition-Heart Failure (BEAT-HF) trial showed a trend towards reduced mortality at 30 days, but not at 180 days, with noninvasive telemonitoring and nurse telephone coaching (NTM-NTC), but no improvement in readmission rates.[10] A more recent meta-analysis conducted in 2015 suggested an overall reduction in all-cause mortality and HF-associated readmissions, however, the authors were unable to identify factors that explained substantial heterogeneity across studies.[15] A contemporaneous overview of systematic reviews concluded that sufficient and high-quality studies to clearly indicate which types of technologies and strategies provide optimum clinical benefit and to which patient subgroups are still lacking.[16] In the most recent review of this topic, Faragli et al. argued that “the profile of patients who can potentially benefit from telemedicine should be further investigated” including in terms of the presence of specific comorbidities, as these can negatively affect the outcomes of patients with HF.[17]

A now well-documented phenomenon, called Heterogeneity of Treatment Effects, explored in a recent article in Annals of Internal Medicine, indicates that treatment effects can vary widely in key subgroups and can differ from the average effect.[18] Given the importance of comorbidities among patients with HF, the purpose of this secondary analysis of the BEAT-HF data was to determine if the association between post-discharge NTM-NTC and readmission and mortality rates varies among HF patients with different comorbidity burdens and to explore if comorbidity subgroups could be used as a potential clinical marker to guide allocation of post-discharge monitoring.

Methods

The experimental design of the BEAT-HF trial has previously been described in detail elsewhere.[10, 19] In brief, the BEAT-HF study was a randomized controlled trial conducted across six academic medical centers in California between October 12, 2011, and September

30, 2013. The study enrolled patients aged 50 years or older who were admitted for acute decompensated HF. All patients provided written informed consent for participation prior to enrollment in the study. The intervention consisted of pre-discharge HF education conducted by a study nurse; regularly scheduled telephone calls from a nurse coach in a centralized call center; NTM of weight, blood pressure, heart rate, and symptoms via a digital-related-symptoms list; and phone calls from the nurse coaches triggered by abnormal results, over a study period of 180 days. For simplicity, the intervention will be referred to as NTM-NTC for the remainder of this manuscript. Usual care consisted of pre-discharge HF education as routine at each medical center, often including a single post-discharge phone call. The original BEAT-HF study reviewed medication use among study participants and found that there were no clinically meaningful differences in the use of angiotensin-converting enzyme inhibitors or angiotensin receptor blockers, β-blockers, digoxin, loop diuretics, or aldosterone antagonists between the intervention and control groups.[10]

This post-hoc secondary analysis includes BEAT-HF participants with known vital status at 180 days post-discharge and non-missing coded comorbid conditions at enrollment admission in the index study (N=1,313). Patients excluded due to missing data on comorbid conditions were significantly younger than those with non-missing data (65.7 years vs. 73.0 years), but they were equally distributed between the NTM-NTC (54.2%) and usual care (51.6%) groups. There were no significant differences between included and excluded patients in gender, race, ethnicity, or Medicaid insurance status in either study arm.

Comorbidity Measure.

Burden of comorbidity was measured by using coded complication/coexisting diagnoses (CCs) from the index admission, following a previously published methodology that produced an index of comorbidity scoreable from coded diagnostic information and specific to HF.[20] The distribution of the sum of comorbid conditions was approximately normally distributed, suggesting that subgroups could be clustered into clinically relevant groups (see Supplemental Figure I). Three subgroups were defined: within one standard deviation (SD) above or below the mean number of CCs as “moderate”, and the 1 SD ± tails as having “low” and “high” burdens of comorbidity, respectively. SD cut-offs were rounded down and up to the nearest whole number for the low and high comorbidity subgroups, respectively, to make the greatest distinction among subgroups.

Statistical Analyses.

Outcomes of interest included 30- and 180-day readmissions assessed for all patients regardless of mortality status; all-cause mortality at 30 and 180 days; and days alive and days alive and out of the hospital at 180 days post-discharge. Numerical variables were summarized by mean and SD and/or range. Categorical variables were summarized by frequencies and percentages. In bivariate analyses, readmission and mortality outcomes were compared across the comorbidity subgroups (Low, Moderate, High) by the Cochran-Armitage trend test.

General linear models (GLMs) were used to evaluate the impact of NTM-NTC on the continuous study outcomes of days alive and days alive and out of the hospital stratified

by comorbidity subgroups. Kaplan-Meier survival curves comparing the NTM-NTC and usual care groups were created for each comorbidity subgroup, with differences between study arms assessed by the Log Rank test. Multivariable Cox regression was used to estimate hazard ratios (HR) and 95% CIs for mortality outcomes within each comorbidity subgroup. A supremum test confirmed proportional hazards. Age and gender were included as covariates in all models.

We first tested the hypothesis that the effect of NTM-NTC on days alive and days alive and out of the hospital would vary with the burden of comorbidity using a general linear interaction model with age and gender included as covariates. The model included a term for the interaction of NTM-NTC with the comorbidity subgroups (a categorical-by-categorical variable interaction), which was significant ($p = 0.032$). Hence, moving forward, we performed separate analyses for the two continuous outcomes within each of the three comorbidity subgroups. Because of the significant interaction, we also analyzed readmission and mortality separately in each of the three comorbidity subgroups. A two-sided 0.05 significance level was used throughout. SPSS version 24 and SAS version 9.4 were used for the statistical analyses.

The BEAT-HF trial was approved by the University of California, Los Angeles (UCLA) institutional review board, and all other study institutions were subject to the UCLA institutional review board review. A data and safety monitoring board was convened for the study and reviewed data during the study enrollment period. All participants gave their informed consent prior to enrollment in the trial. The study was registered at clinicaltrials.gov (NCT01360203).

Results

Description of the Sample.

There were 708 males (53.9%) and 605 females (46.1%) included in this analysis (Table 1). Average age was 73.2 years (SD: 12.1; range 50–103). Race was identified as White 65.4%; Black/African American 21.6%; and Other 13.0%. There were no significant differences in demographic characteristics between the NTM-NTC and usual care groups (see Supplemental Table I). Table 1, below, displays the characteristics of the total sample and stratified by each of the three comorbidity subgroups. The low comorbidity subgroup was younger and less likely to have Medicaid as a primary or secondary insurance payer.

Burden of Comorbidity.

Patients had a mean of 5.7 comorbidities (SD: 2.4; range: 0–16). The distribution of the burden of comorbidity was approximately normal (Supplemental Figure I). Burden of comorbidity subgroups were defined as: Low (0–2 comorbidities), n=98 (7.5%); Moderate (3–8 comorbidities), n=1,059 (80.7%); and High (9+ comorbidities), n=156 (11.9%). The most prevalent comorbidity was hypertension (81.3%). Supplemental Table II includes a complete list of comorbid conditions identified in the sample. Higher burden of comorbidity was positively associated with 30-day readmission, 180-day readmission, 30-day mortality,

180-day mortality, and inversely related to days alive in the 180-day period of observation (Table 2).

Intervention Effects Overall and in Comorbidity Subgroups.

Consistent with the main results of the BEAT-HF study,[10] there were no differences in this sub-study in 30-day and 180-day readmission rates between intervention and control groups (data not shown). There were also no significant main effects of treatment group for the outcomes of Days Alive (F=1.09, p=0.297) or Days Alive and Out of Hospital (F=1.01, p=0.315) (see Table 3a). However, general linear model analysis demonstrated a significant interaction effect between comorbidity burden and NTM-NTC on the mean number of days alive and days alive and out of the hospital (Table 3b). Within the high comorbidity subgroup, patients who received NTM-NTC had significantly more days alive on average (160.1 vs 140.3, F=3.562, p=0.029) and more days alive and out of the hospital (152.0 vs 133.2 days; F = 3.13, p=0.044) than the usual care group. The NTM-NTC group survived 20 more days on average (out of the 180-day study period) than the usual care group. The mean number of days alive and out of the hospital was also 19 days greater in the NTM-NTC group than in the usual care group.

Survival analysis did not demonstrate significant differences in the number of days alive between the NTM-NTC and usual care groups within either the low or moderate comorbidity subgroups (Figure 1). Within the high comorbidity subgroup, the risk of death was cut in half for the NTM-NTC group (HR: 0.51; 95% CI: 0.27–0.98; p = 0.039) with the survival curve for this group closely resembling that of the low and moderate comorbidity subgroups. While a pre-intervention (day 0 – in hospital) difference is visible on this graph, the separation of curves becomes more distinct by 30 days and 180 days post-discharge. The difference in number of deaths between the control and intervention groups was four while in the hospital, nine at 30 days post-discharge and 12 at 180 days post-discharge.

The NTM-NTC intervention was not associated with the likelihood of readmission for any comorbidity subgroup. However, patients in the high comorbidity subgroup who received NTM-NTC had a significantly lower likelihood of mortality at both 30 days (3.8% vs.14.8%; HR: 0.25, 95% CI: 0.07–0.90) and 180 days (18.2% vs. 32.5%; HR=0.51, 95% CI=0.27–0.98) after adjusting for age and gender (Table 4).

Dose of Intervention.

Within the intervention group, there was no evidence of differences in the amount of intervention received between comorbidity subgroups. There were no significant differences between subgroups in number of phone calls, total minutes on the phone, or days with NTM-NTC data points collected from patients; and participants in all comorbidity subgroups were equally likely to be active users of the intervention (Table 5).

Discussion

NTM-NTC was associated with a reduction in 30-day and 180-day mortality in patients with high comorbidity burden (≥ 9 CC’s) without affecting readmission rates in this multicenter trial. The intervention appeared to reduce mortality in the high comorbidity subgroup to

nearly the same level as that of patients in the moderate comorbidity subgroup (3–8 CC's). This finding is notable given the trend towards 30-day mortality reduction (unadjusted HR=0.61, 95%CI, 0.37–1.02, P = .06; adjusted HR=0.53, 95% CI, 0.31–0.93, P = .03) for the intervention arm in the original BEAT-HF trial.[10] Mortality rates were significantly lower with NTM-NTC in the high comorbidity subgroup, which translated to more days alive and out of the hospital for these patients.

Care transition programs have shown promise in helping patients transition safely to the home.[21–23] This analysis demonstrates that telemedicine can improve survival for those at higher risk of mortality related to increased burden of comorbid conditions. NTM-NTC provides timely, objective information without the need for invasive procedures or implantable monitoring devices. In the patient with a high burden of comorbidity, this may reduce the need for procedures and potential complications. As illustrated during the COVID-19 pandemic, healthcare systems benefit from maintaining care quality despite restrictions on patient travel, marked reductions in community support, limitations in resources such as medical staff and supplies, and major alterations to patients' ways of living. NTM-NTC accomplishes this by maintaining remote access to high-quality HF care without additional physical patient contacts, and without significant demands on the healthcare system. The number of data points and the number and length of phone calls were similar across comorbidity subgroups, which made the study findings surprising, as most would expect greater need for care coordination in patients with high comorbidity burden. Future studies may clarify the ideal frequency of data monitoring and medical intervention/nursing response workflows to maximize mortality reduction in this population.

The reduction in mortality in the high comorbidity subgroup who received NTM-NTC was not accompanied by a difference in readmission rates compared to those who received usual care. This finding in the high comorbidity subgroup is supported by the differences in average days alive (160.1−140.3=19.8) and average days alive out of the hospital (152.0−133.2=18.8), which were very similar. These results suggest that the mortality benefit of NTM-NTC in patients with high comorbidity burden may not be associated with increased use of inpatient services. Much effort in the United States has focused on reducing HF readmissions as a surrogate for high-quality care. The Medicare Hospital Readmissions Reduction Program (HRRP) penalizes hospitals for high rates of readmission for HF and other chronic conditions.[2, 24] As a result, readmission rates for HF have declined in the United States, but this reduction has also been occurring around the world in countries without penalty programs.[2, 25, 26] Unfortunately, the HRRP has not demonstrated consistent improvement in outcomes and potentially even resulted in worsening outcomes for patients.[24, 27] Improving overall quality of care, including improving survival and quality of life, may involve acceptance of readmissions as part of a broader strategy to improve outcomes, and further research will help delineate these trade-offs.

The additional days alive and out of the hospital gained by patients in the high comorbidity subgroup who received NTM-NTC are particularly important for patients with advanced disease. Since many patients with HF are not candidates for interventions such as transplant and device therapy, the potential for post-hospitalization care is vital for increasing quality of life for these patients by allowing for more time at home. This also reduces the burden on

care providers and the healthcare system. Future studies examining NTM-NTC in end-stage HF patients may help to illuminate this benefit. Also, nationwide multicenter research may allow for a more generalizable determination of high comorbidity population subgroups that may consistently benefit from intervention across differing health systems.

Our approach of using comorbidity stratification by CCs has been previously validated in a national HF population,[20] and it requires no additional data collection beyond what is automatically collected for Medicare patients. However, the specific comorbidity count cutoffs used in this study were derived from our own data from six sites. Future nationwide research may allow for a more generalizable determination of high comorbidity subgroups that may consistently benefit from NTM-NTC interventions.

Patients with HF in low and moderate comorbidity subgroups did not significantly improve from NTM-NTC. This finding may reflect inadequate tailoring of the intervention to the needs of patients with different levels of comorbidity, inadequate power to find effects in subgroups with lower risk, or a true lack of effect in relatively low-risk patients. Because BEAT-HF was not powered to detect within-stratum effects on readmissions and mortality, the confidence intervals shown in Table 4 are wide. The BEAT-HF study followed patients only up to 180 days post discharge. It is possible that the effects of NTM-NTC might show benefit in low and moderate comorbidity subgroups in a longer follow-up study.

Novel developments in wearable technology may demonstrate the capacity to augment noninvasive data collection and improve quality of care at minimal cost.[28] Meanwhile, invasive monitoring approaches such as pulmonary artery pressure monitors may prove useful in select patients.[8] Future studies of stratified care transitions incorporating NTM-NTC may clarify the ideal match between patients and care transition programs. For example, supportive care medicine programs for HF patients with moderate to high comorbidity may offer opportunities to address end of life care in the context of quality-of-life endpoints.[29, 30] Additionally, future studies are needed to evaluate NTM-NTC in select environments such as rural populations and in cases of natural disasters such as pandemics that may limit doctor-patient contact.

Limitations.

This study was a secondary analysis of a multi-site randomized controlled trial. Because it included a sub-sample of participants with complete coded index admission diagnoses and outcome data, bias due to missing data may have been introduced into the comparisons with unknown effect. We found only a difference in average age between those patients included in the analysis and those excluded; patients with missing data were evenly distributed among comorbidity subgroups and treatment arms.

In conclusion, NTM-NTC improved survival and days out of the hospital among HF patients with high comorbidity burden, and successful targeting of this patient population may improve outcomes and extend life.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Biography

Abbreviations:

BEAT-HF	Better Effectiveness After Transition-Heart Failure
CC	complication/coexisting diagnosis
CI	confidence interval
GLM	general linear model
HF	heart failure
HR	hazard ratio
HRRP	Hospital Readmissions Reduction Program
NTM	noninvasive telemonitoring
NTM-NTC	noninvasive telemonitoring and nurse telephone coaching
SD	standard deviation

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Highlights

- Post-discharge telemonitoring/telephone coaching was evaluated in heart failure
- Post-discharge telemonitoring may not benefit all heart failure patients equally
- More beneficial to heart failure patients with high burden of comorbidity
- Improved survival among patients with higher comorbidity who received intervention
- Improved number of days alive and out of hospital post-discharge in this subgroup

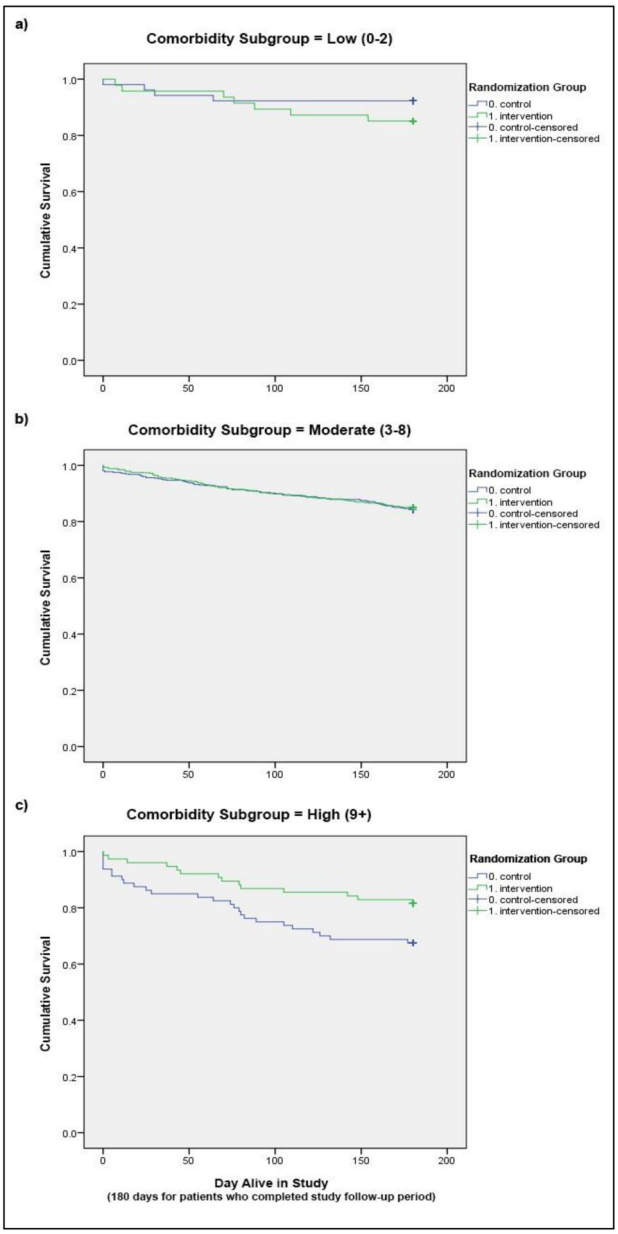

Figure 1.

Kaplan Meier Survival Curves for Days Alive within Three Comorbidity Subgroups (N = 1,313)

Table 1.

Demographics for All Study Patients and by Comorbidity Subgroup

		Comorbidity Subgroup			
	Total	**Low**	**Moderate**	**High**	***P***
	(N = 1,313)	**(n = 98)**	**(n = 1,059)**	**(*n*=156)**	
Age in Years (SD)	73.2 (12.2)	71.3 (13.1)	73.1 (12.2)	75.2 (10.6)	0.035
Age Over 80 Years	36.0 %	26.6 %	36.4 %	39.1 %	0.154
Gender Female	46.1 %	42.9 %	45.1 %	54.5 %	0.073
Race					0.897
White	65.5 %	63.3 %	65.4 %	67.3 %	
Black/African American	21.6 %	21.4 %	21.6 %	21.8 %	
Other/Multiple	12.9 %	15.3 %	12.9 %	10.9 %	
Ethnicity Hispanic	6.7 %	7.1 %	6.9 %	5.1 %	0.701
Medicaid Primary or Secondary Payer	38.6 %	27.6 %	38.7 %	44.9 %	0.022
SD: standard deviation					

Table 2.

Burden of Comorbidity Associated with Patient Outcomes

Outcome	Burden of Comorbidity Subgroup				
	Low	Moderate	High	Statistical Test	*P*
	(*n*=98)	(*n*=1,059)	(*n*=156)		
% 30-day Readmission	8.1	22.5	31.4	X^2=18.08 *	<0.001
% 180-day Readmission	31.3	51.4	64.1	X^2=25.00 *	<0.001
Days Alive †, +/− (SD)	166.3 (41.8)	164.3 (43.0)	149.8 (58.0)	F=7.41	0.001
Days Alive and Out of Hospital †, +/− (SD)	164.3 (42.6)	159.3 (44.8)	142.2 (58.4)	F=10.35	<0.001
% 30-day Mortality	5.1	4.1	9.6	X^2=4.58 *	0.032
% 180-day Mortality	11.1	15.3	25.6	X^2=11.38 *	0.001

*Chi-square statistic reported is Cochran-Armitage linear-by-linear association.

†Days out of the 180-day study period.

SD: standard deviation

Table 3a.

Intervention Effects on Mean Days Alive and Mean Days Alive and Out of the Hospital (Estimated Means Adjusted for Age and Gender Effects)

Outcome	Treatment Group	
	Control	Intervention
	(*n*=659)	(*n*=654)
Mean Days Alive * (SE)	161.4 (1.74)	164.0 (1.75)
Mean Days Alive and Out of Hospital * (SE)	156.3 (1.80)	158.9 (1.80)

* Days out of the 180-day study period

SE: standard error

Table 3b.

Intervention Effects within Burden of Comorbidity Subgroups on Mean Days Alive and Mean Days Alive and Out of the Hospital (Estimated Means Adjusted for Age and Gender Effects)

Outcome	Treatment Group	Burden of Comorbidity Subgroup		
		Low	Moderate	High
		(*n*=98)	(*n*=1,059)	(*n*=156)
Mean Days Alive * (SE)	Control	167.2 (6.2)	164.0 (1.9)	140.3 (5.0) †
	Intervention	163.9 (6.5)	164.5 (1.9)	160.1 (5.1) †
Mean Days Alive and Out of Hospital * (SE)	Control	165.9 (6.4)	158.9 (2.0)	133.2 (5.1) †
	Intervention	161.2 (6.7)	159.7 (2.0)	152.0 (5.2) †

* Days out of the 180-day study period

† Statistically significant difference between NTM-NTC and Usual Care groups

SE: standard error

Table 4.

Intervention Effects within Burden of Comorbidity Subgroups on Likelihood of Mortality at 30 Days and 180 Days (Hazard Ratios Adjusted for Age and Gender Effects)

Outcome		Burden of Comorbidity Subgroup		
		Low	Moderate	High
		(n=98)	(n=1,059)	(n=156)
30-day Mortality	Control *n*	3	24	12
	Intervention *n*	2	19	3
	Hazard Ratio (95% CI)	0.59 (0.10–3.66)	0.78 (0.43–1.42)	0.25 * (0.07–0.90)
180-day Mortality	Control *n*	4	83	26
	Intervention *n*	7	79	14
	Hazard Ratio (95% CI)	1.72 (0.50–5.89)	0.94 (0.69–1.28)	0.51 * (0.27–0.98)

* Statistically significant difference between NTM-NTC and Usual Care groups

CI: confidence interval

Table 5.

Dose of NTM-NTC Received by Intervention Group Patients Stratified by Burden of Comorbidity Subgroups

Intervention Dose Measures	Burden of Comorbidity Subgroup			P value
	Low	Moderate	High	
	(n=98)	(n=1,059)	(n=156)	
Number of phone calls	4.7	5.4	4.9	0.103
Total minutes on phone	93.8	93.5	82.5	0.285
Days with NTM-NTC data points	77.4	84.5	77.0	0.565
% Active users (1+ reading per month)	52.8%	55.9%	49.4%	0.520