Congestive heart failure disease management program: 1-Year population experience from a tertiary center heart failure registry in Saudi Arabia

CrossMark

Khal Salem [a,*], Dania Fallata [a], Maha ElSebaie [a,b], Ahmad Montasser [a], Khaled ElGedamy [a], Osama ElKhateeb [a]

[a] Cardiac Centre, King Abdullah Medical City (KAMC), Makkah
[b] Zagazig University, Cairo

[a] Saudi Arabia
[b] Egypt

Aims: We aimed to evaluate congestive heart failure (CHF) multidisciplinary disease management program (DMProg) impact on mortality, readmission rates, length of stay (LOS), and gender health characteristics.

Methods and results: This was a quasi-observational, pre- and post-trial with a parallel nonequivalent group. We enrolled 174 inpatients having CHF with reduced ejection fraction and New York Heart Association (NYHA) Class II–IV, and a total of 197 hospital admissions. A comparative follow-up was performed from 15 December 2014 to 15 December 2015. Among 197 consecutive hospital admissions, 76 (39%) were included in the preintervention or usual care group and 121 (61%) were assigned to the postintervention group. After 1 year, in comparison with the preintervention group, the postintervention group had shorter average LOS in days (7.6 days vs. 11.1 days, $p < 0.002$), lower 1-year readmission rate (36% vs. 57%, $p < 0.003$), and lower in-house mortality (1.6% vs. 7.8%, $p = 0.03$), but similar baseline mortality scores (38.2 vs. 38.6, $p = 0.7$), 30-day and 90-day readmission rates (15% vs. 18.3%, $p = 0.62$ and 27.6% vs. 30%, $p = 0.65$), and 30-day readmission risk score (24.9% vs. 26.2%, $p = 0.09$). By regression analysis, the DMProg intervention was an independent factor for 1-year readmission reduction ($p = 0.001$). Kaplan–Meier survival analysis favored the postintervention group (log-rank, $p < 0.001$).

Conclusion: DMProg significantly decreased 1-year readmission rates, LOS, and in-house mortality.

P.O. Box 2925 Riyadh – 11461KSA
Tel: +966 1 2520088 ext 40151
Fax: +966 1 2520718
Email: sha@sha.org.sa
URL: www.sha.org.sa

Production and hosting by Elsevier

Introduction

Congestive heart failure (CHF) is one of the leading causes of hospitalization among the elderly population of Europe and North America. However, information on the developmental strategies, components, and outcomes in the Middle Eastern population is limited [1] and has been traditionally classified under the 'others' subgroup.

In industrialized countries, CHF utilized 1–2% of the total health expenditure and exceeded the combined costs of acute coronary syndrome and cancer [2]. It has higher mortality rates than AIDS and all types of cancer [3], lower median survival in males (1.7 years) than in females (3.2 years), and 30–50% of 6-month readmission rate [3,4].

Over the past 20 years, best CHF management practices have evolved into the establishment of a multidisciplinary team, development of an outpatient clinic, performance of a 72-hour postdischarge phone call, implementation of different templates for standardized clinical pathways [3,5,6], and introduction of guideline-directed medial therapy (GDMT) [3,4,7]. GDMT refers primarily to Class I-recommended medications, including angiotensin-converting enzyme inhibitors (ACEI) or angiotensin-2 receptor blockers (ARBs), beta blockers (BB), diuretics, aldosterone, and in selected patients, hydralazine–nitrate combination. Bisoprolol, carvedilol, and extended-release metoprolol are the mainstays of pharmacologic BB therapy for heart failure with reduced ejection fraction (HFrEF). Multidisciplinary team approach programs have improved functional status, decreased 1-year rehospitalization from 57% to 36%, shortened length of stay (LOS), and emphasized compliance [8–10].

This study aimed to evaluate the impact of a heart failure disease management program (DMProg) model on mortality; readmission rates at 30 days, 90 days, and 1 year; LOS; gender-based response and characteristics in a Middle Eastern population. In addition, we aimed to propose a new program framework using prospective data analysis from the Makkah Heart Failure Registry (Mak-HFR).

Materials and methods

Study design

This was a quasi-observational, pre- and post-trial with a parallel nonequivalent group. We enrolled 174 inpatients having CHF with reduced ejection fraction and New York Heart Association (NYHA) Class II–IV, and a total of 197 hospital admissions. Starting 15 December 2014, we enrolled consecutive patients admitted to the cardiac department. Inclusion criteria were HFrEF of 40–45% or less, based on echocardiographic report; age range of 18–70 years and NYHA functional Class II–IV. The exclusion criteria included cardiogenic shock; mechanical ventilatory support; unstable coronary artery disease; acute myocarditis; planned cardiac surgery, including transplantation; severe aortic stenosis; and significant comorbid conditions, such as malignancy and severe disabling obstructive lung disease.

We followed-up the clinical course of the initial 76 (usual care group) and 121 (intervention group) hospital admissions from the time of referral until discharge. LOS was evaluated and readmission root cause analysis was performed. Data were utilized to develop customized clinical pathway and standardized tools. Performance outcome measures and control charts were monitored on the next 121 patients admitted to the hospital (intervention group).

We calculated the predicted mortality score using the Get with the guidelines-HF (GWTG-HF) risk model and the 30-day readmission risk score for heart failure online calculator; both are advocated by the American Heart Association (AHA) [11].

The program structure consisted of the following three main components: (1) an executive sponsor that was aligned with the strategic direction of the organization and allocated resources; (2) a nurse specialist coordinator of care and a well-trained, high functioning team that applied the best clinical heart failure practice tools; and (3) a cardiologist who served as the chairman of the program.

Abbreviations

NYHA	New York Heart Association
DMProg	disease management program
CHF	congestive heart failure
GDMT	guideline-directed medial therapy
HFrEF	heart failure with reduced ejection fraction
Mak-HFR	Makkah heart failure registry
DAMA	discharge against medical advice
LOS	length of stay
BB	beta blocker
ACEI	angiotensin converting enzyme inhibitor
ARB	angiotensin receptor blockers
MRA	menieralo-corticoid receptor antagonist

Intervention

The core intervention components comprised 4-day clinical pathway, standardized tools, 72-hour postdischarge phone call, and early postdischarge appointment in a one-site/nurse/physician heart failure clinic. We monitored the 4-day cumulative defects of a two-component clinical pathway. The pathway functioned as a monitoring checklist and was not part of the medical record. The first pathway component was task-directed and included expected outcomes, goals, activity level, as well as diagnostic, nutritional, therapeutic, educational, and transitional care assessment and needs. The second clinical pathway component included team member role items. The pathway checklist was used only for the first 4 days of hospitalization, after which monitoring was based on 'increased LOS root cause analysis' and an action plan. Root cause analysis was performed for every readmitted patient. The nurse coordinator used a standardized six-step checklist during daily rounds and measured the GWTG-HF risk model, which was advocated by the AHA to predict in-hospital mortality [12,13] and the heart failure readmission risk score [14].

Patient education was part of the intervention and focused on symptom recognition, ideal weight definition, and medication reconciliation. Targeting a total of 60 minutes of education throughout hospitalization, we used interactive workbooks and teach-back techniques. Later on in the study, we added an individualized A4-sized take-home action plan for each patient at Grade 4 education level.

Transition of care was done through a 72-hour postdischarge phone call that was performed by the nurse coordinator, followed by arranging for appointment in the heart function clinic 1–2 weeks after discharge. The expected outcomes from phone calls were reinforcement of self-management and recognition of worsening symptoms by the patient; screening postdischarge heath status and directing patients towards continuation of home stay, and early scheduling of appointment at the heart failure clinic or direct admission to the hospital, in case of unmanageable deterioration. In this study, we chose not to use patient self-treatment with diuretic sliding scale as part of the education curriculum or transition of care.

One-nurse/one-physician/one-site clinic (triple-one clinic)

Each patient in the intervention group was invited to the heart failure clinic 1–2 weeks after discharge. The clinic coordinator performed as-needed consultation with the rest of the team that included a pharmacist, a dietician, an educator, and a psychologist. The physician and nurse reviewed the medications and revised the patient logbook. The outputs of the clinic visit were referral back to the primary physician, follow-up if readjustment of medications was needed, emphasis on self-management skills, and reinforcement of education.

Statistical analysis

Data analysis was performed using the Minitab statistical analysis software version 17.2.1 (Minitab company, Pennsylvania, USA). Statistical significance was determined by the Student t test, with a two-sided p value < 0.05; one-sided t-test and upper limit of confidence interval were used to analyze the in-house mortality data. The non-normally distributed data on LOS were transformed using the Box–Cox plot methodology and were then analyzed by the Student t test. Analysis of variance was used to assess the effects of the intervention. We used backward stepwise multiple linear regression analysis to identify the determinants of LOS variation. In this study, we referred to the combined in-house mortality and 30-day readmissions as the 'program 30-day event-free period'.

Results and discussion

Outcome measures

In the Mak-HFR, CHF represented 10% of all cardiac hospital admissions; 80% of them were HFrEF. We calculated the predicted mortality score using the GWTG-HF risk model that has been provided by the AHA; GWTG-HF risk model predicts in-house mortality using a score ranging from 0 to100 [13]. We found a clear mortality benefit in the intervention group. The calculated expected mortality based on average mortality score was 38.5 versus 38.2 points (equivalent to 1–5% of the expected mortality rate) in the control and intervention groups, respectively; whereas the actual mortality rate in the preintervention group was higher (7.8%), compared with 1.6% in the postintervention group. Readmission rates had a nonsignificant decreasing trend after 30 days (from 18% to 15%; $p = 0.62$) and 90 days (from 30% to 27%; $p = 0.65$). However, compared with the preintervention group, the postintervention group had lower 1-year readmission rate (36% vs. 57%; $p < 0.003$), shorter LOS (11.7 vs. 7.6 days;

$p = 0.002$), and lower rate of discharge against medical advice (DAMA) (0% vs. 4.4%; $p < 0.001$).

The top reasons for longer LOS in the usual care group were delayed symptomatic improvement (30%), absence of strict daily weight measurements (15.4%), and delayed follow-up on consultation requests (15%). However, the postintervention group had comorbidities (17.9%), drainage requirements (11.4%), and submaximal medication dosage (10.3%). The LOS regression analysis model confirmed that the DMProg intervention was one of the three independent factors of shortening LOS ($p = 0.008$); the other two factors were the absence of atrial fibrillation ($p = 0.001$) and the use of furosemide diuretic ($p = 0.013$).

Discharge medications

Upon discharge from the hospital, following medications were administered to the patients: ACEI (47.7%), hydralazine (26%), BBs (86%), spironolactone (48%), furosemide (81%), nitrates (38%), ARB (11.7%), and digoxin (7.6%). There was a nonstatistically significant increased utilization of ACEI, BB, furosemide, and spironolactone, but there was no impact on hydralazine, nitrate, or ARB ($p > 0.05$ for all variables). The number of patients on hydralazine and nitrate combination was 22.8%. We performed a subgroup analysis comparing ACEI or ARB with combined hydralazine and nitrate treatment, in addition to BBs. In both arms, there was no difference in the test of equal variance of a combined 30-day readmission and in-house mortality event free survival

```
┌──────────────────────────────────────────────────────────────────┐
│ Cardiac admission to the cardiac ward, CCU, chest pain unit,        │
│ day care unit (n = 3460)                                           │
└──────────────────────────────────────────────────────────────────┘

┌──────────────────────────────────────────────────────────────────┐
│ Admissions with an ICD 9 diagnosis of congestive heart failure,     │
│ including both HFrEF and HFpEF (n = 362)                           │
└──────────────────────────────────────────────────────────────────┘

┌──────────────────────────────────────────────────────────────────┐
│ Number of admitted HFrEF patients (n = 292)                        │
└──────────────────────────────────────────────────────────────────┘

┌──────────────────────────────────────────────────────────────────┐
│ Admissions based on the enrolment criteria (n = 197)               │
└──────────────────────────────────────────────────────────────────┘
```

Age 18–70 years, symptomatic heart failure (NYHA Class II–IV), and left ventricular ejection fraction of 40%, as measured by echocardiography

Cardiogenic shock; mechanical ventilatory support; unstable coronary artery disease; acute myocarditis; planned cardiac surgery, including transplantation; severe aortic stenosis; significant co-morbid conditions, such as malignancy or severe obstructive lung disease; and age <18 and >70 years

Post intervention Group from April to December 2015 (n = 121)

Pre intervention group from January to March 2015 (n =76)
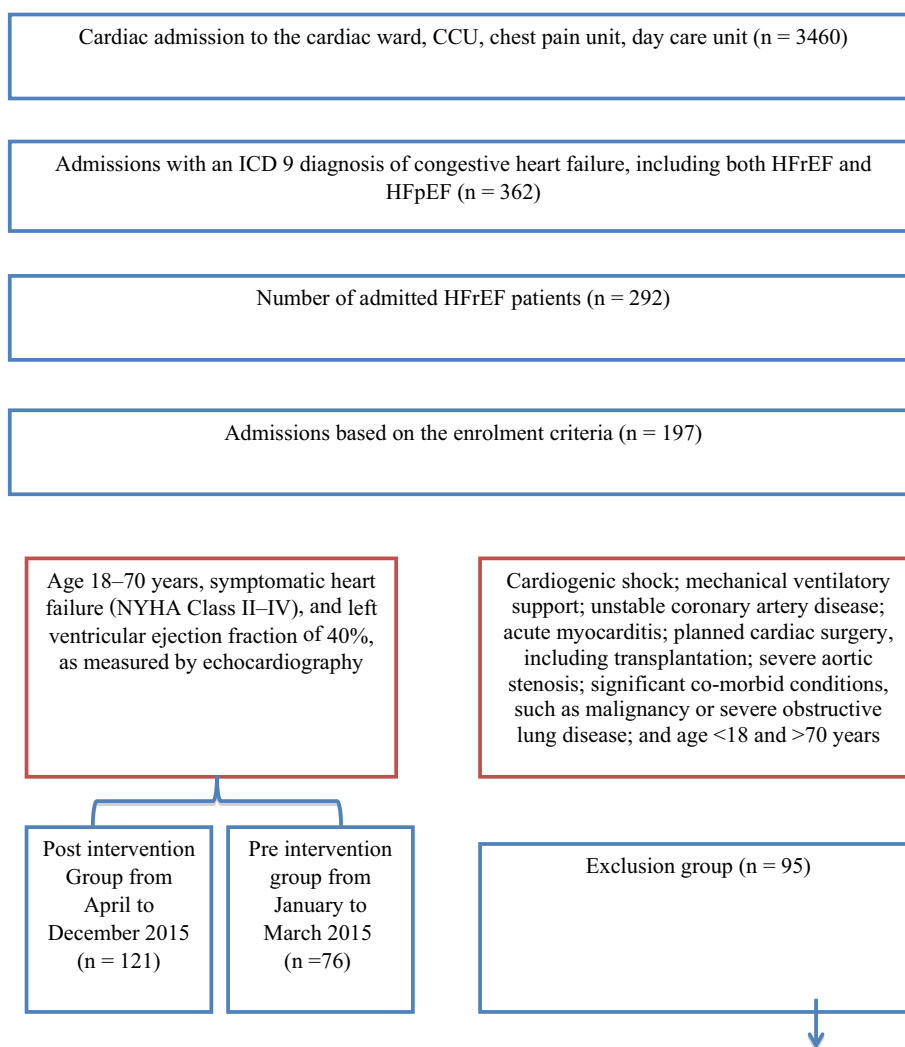
Exclusion group (n = 95)

Figure 1. Patient enrolment flow chart. CCU = coronary care unit; ICD = implantable cardiac defibrillator; HFrEF = heart failure with reduced ejection fraction; HFpEF = heart failure with preserved ejection fraction; NYHA = New York Heart Association.

between the ACEI/ARB/BB and hydralazine/nitrate/BB groups ($p = 0.857$; Fig. 1). That mentioned, the interpretation was challenged by the following evidence-based target average daily doses: ACEI (perindopril, 3.7 mg), BB (bisoprolol, 3.6 mg; carvedilol, 12.8 mg), ARBs (valsartan 77.5 mg; irbesartan, 214 mg), furosemide (63.1 mg), spironolactone (18.9 mg), hydralazine (96.6 mg), dinitrate (35 mg), and digoxin (0.112 mg).

The discharge medications in this population were characterized by the use of ACEI (47%), hydralazine (26%), nitrates (38%), and a combination of hydralazine and nitrates (22%). The use of ARBs (11.9%) and BBs (86%) was as expected.

72-hour phone call

Only 63% (47 of 103) of patients answered the 3-day postdischarge phone calls; 67% of those who answered felt well and followed instructions, 17% had CHF symptoms, 7% had nonlife-threatening bleeding complications, 4% did not follow instructions, and 4% required direct hospital admission. Of the eight CHF symptoms that were reported, six (75%) were successfully managed by phone, whereas two (25%) required outpatient consultation the following day at the triple-one clinic. The low reply rate of the phone call was a challenge of complex nature. After discharge, each patient received two 72-hour phone calls during the weekday working hours. We used a ''no-reply'' hospital owned dedicated landline. The contact numbers that were available on record do not necessarily belong to patients themselves; the majority belonged to the family-selected next of kin or the decision-making individuals, and subsequently direct talking to some of the patients failed. Moreover, some patients were not willing to answer a nonfamiliar private phone number. Moreover, the sleep–awake cycle of the patient somehow interfered with the ability to designate proper calling time during the 8:00 AM to 16:00 PM weekday hours. The authors' current opinion is that phone calls are resource-intensive, difficult to measure, and of unclear cost-effectiveness impact; moreover, further data analysis is required when we achieve a larger sample size.

Cost effectiveness

Although evaluation of cost effectiveness was not an aim of the study, the cost savings might be due to the reduction of annual hospital occupancy and a 15% average reduction of readmission rate and hospitalization. However, the cost

effectiveness of this DMProg in the Middle East warrants future research.

Lessons learned

In the Middle East, a literature review revealed a 30-day mortality of 5.3–9% (12). In this study, HFrEF DMProg shortened LOS; decreased in-house mortality and 1-year readmission rates; did not negatively affect gender-specific health-care disparity; did not improve the combined 30-day and in-house mortality event rates; and may result in cost saving through reduction of bed occupancy and shortened LOS. The triple-one heart failure clinic was an efficient and effective model. Hydralazine and nitrate therapy may have mortality and 30-day readmission benefits that were not inferior to those of ACEI/ARB treatment. The 2013 ACCF/AHA Heart Failure Guidelines state the use of a combination of hydralazine and isosorbide dinitrate as Class I (in combination with ACEI) or Class IIa (if ACEI cannot be given) recommendations for African Americans, but there are no similar recommendations for the Middle Eastern population. Further a large-scale, randomized controlled trial is recommended. Therefore, this study proposed a structural program triad of: (1) executive sponsor; (2) coordinator of care; and (3) a well-trained and properly tooled cardiologist-led team as a valid framework for a heart failure management program. This model provided evidence on long-term, sustainable outcomes that exceeded the initial 30 days of implementation.

This study demonstrated no statistically significant improvement of the 30-day or 90-day readmission rates; however, there was improvement of the 1-year readmission rate. We attributed this positive long-term impact of the DMProg to the expected enhanced education and self-management skills the patients had acquired. The initial 60-minute education during hospitalization, the quick symptom-recognition during the phone calls, and the further reinforcement that happened if the patients were readmitted could be applied to the multidisciplinary team performance also. Such a patient-multidisciplinary team learning curve hypothesis deserves further validation.

Strengths and limitations of the study

The study may shed some light on the characteristics of a Middle Eastern ethnic group of CHF patients who have traditionally been referred to as part of the 'others' category in medical literature. In addition, it may open the field for devel-

oping countries; provide a triad of structured disease management; and advocate the use of DAMA as a patient experience performance indicator, a statistical process control, and capability charts that uses evidence-based customized tools.

The improvement in mortality from cardiac death was probably overestimated because of the small sample size and because the exclusion criteria did not include active coronary artery disease, which may have resulted in unintentional exclusion and different The International Classification of Diseases-9 (ICD-9) coding. Moreover, the 80% of HFrEF representation was higher than international norms, raising the possibility of unintentional selection bias. The study pointed out some areas of success, but it did not identify the primary cause of process improvement. These findings may suggest a multifactorial positive impact of the program structure, the framework triad, standardized tools, team approach methodology, human factors, and the implementation of clinical pathways on the long term outcome of the CHF disease management program. Moreover, the multidisciplinary team was extensively involved in the outpatient management of the enrolled patients and this may have contributed to the more obvious 1-year outcomes compared with the short-term outcome, and such a hypothesized favorable impact of multidisciplinary outpatient care on the long-term outcome would need to be validated by further studies. Finally, although the program resulted in increased use of ACEI and BB, decreased use of hydralazine and digoxin, and equivocal use of ARB, these changes were statistically insignificant, indicating that a program impact on the prescribing culture of physicians may be an opportunity for improvement.

Acknowledgments

References

[1] AlHabib KF, Elasfar AA, AlBackr H, AlFaleh H, Hersi A, AlShaer F, et al.. Design and preliminary results of the heart function assessment registry trial in Saudi Arabia (HEARTS) in patients with acute and chronic heart failure. Eur J Heart Fail 2011;13(11):1178–84.

[2] Rich MW, Beckham V, Wittenberg C, Leven CL, Freedland KE, Carney RM. A multidisciplinary intervention to prevent the readmission of elderly patients with congestive heart failure. N Engl J Med 1995;333(18):1190–5.

[3] Di Salvo TG, Stevenson LW. Interdisciplinary team-based management of heart failure. Dis Manage Health Outcomes 2003;11(2):87–94.

[4] Go AS, Mozaffarian D, Roger VL, Benjamin EJ, Berry JD, Blaha MJ, et al.. Heart disease and stroke statistics—2014 update. Circulation 2014;129(3):e28–e292.

[5] Hawe P, Shiell A, Riley T. Complex interventions: how ''out of control'' can a randomised controlled trial be? BMJ 2004;328(7455):1561–3.

[6] Panella M, Marchisio S, Gardini A, Di Stanislao F. A cluster randomized controlled trial of a clinical pathway for hospital treatment of heart failure: study design and population. BMC Health Serv Res 2007;7(1):1–7.

[7] Holst DP, Kaye D, Richardson M, Krum H, Prior D, Aggarwal A, et al.. Improved outcomes from a comprehensive management system for heart failure. Eur J Heart Fail 2001;3(5):619–25.

[8] Hunt SA, Baker DW, Chin MH, Cinquegrani MP, Feldmanmd AM, Francis GS, et al.. ACC/AHA guidelines for the evaluation and management of chronic heart failure in the adult: executive summary. A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to revise the 1995 Guidelines for the Evaluation and Management of Heart Failure). Circulation 2001;104(24):2996–3007.

[9] Philbin EF. Comprehensive multidisciplinary programs for the management of patients with congestive heart failure. J Gen Intern Med 1999;14(2):130–5.

[10] Yancy CW, Jessup M, Bozkurt B, Butler J, Casey DE, Drazner MH, et al.. ACCF/AHA guideline for the management of heart failure. Circulation 2013;128(16):e240–327.

[11] Hersh AM, Masoudi FA, Allen LA. Postdischarge environment following heart failure hospitalization: expanding the view of hospital readmission. J Am Heart Assoc 2013;2(2):1–14. http://dx.doi.org/10.1161/JAHA.113.000116.

[12] American Heart Association (2015). Get With The Guidelines. Scientific Publications and Program Results. Available from: http://www.heart.org/HEARTORG/Professional/GetWithTheGuidelines/Get-With-The-Guidelines-Scientific-Publications-and-Program-Results_UCM_306758_Article.jsp – V3U2yFc3JFI. [Accessed March 10, 2016].

[13] Peterson PN, Rumsfeld JS, Liang L, Albert NM, Hernandez AF, Peterson ED, et al.. A validated risk score for in-hospital mortality in patients with heart failure from the American Heart Association get with the guidelines program. Circ Cardiovasc Qual Outcomes 2010;3(1):25–32.

[14] Keenan PS, Normand SL, Lin Z, Drye EE, Bhat KR, Ross JS, et al.. An administrative claims measure suitable for profiling hospital performance on the basis of 30-day all-cause readmission rates among patients with heart failure. Circ Cardiovasc Qual Outcomes 2008;1(1):29–37.