Effects of a structured heart failure program on quality of life and frequency of hospital admission in Saudi Arabia

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ABSTRACT

Objectives: To compare the quality of life (QOL) and frequency of hospital admission (FHA) in the past 4 months between congestive heart failure (CHF) patients involved in a structured heart failure program (HFP) compared with waitlisted controls.

Methods: This study, employing an ex-post-facto comparative cross-sectional design, involved 80 patients with CHF (40 in the HFP and 40 controls). Those in the HFP had been enrolled for at least 4 months. Controls were waiting to be enrolled in the program. Participants completed a questionnaire assessing demographic, social/cultural, psychological, and CHF-related physical health characteristics, along with the primary dependent variables, QOL and FHA. Bivariate and multivariate analyses assessed differences between those in the HFP and controls.

Results: Congestive heart failure patients in the HFP were significantly less likely than the control group to score below the median on heart failure-specific QOL, controlling for other variables (OR=0.83, 95% CI: 0.82-0.95, p=0.007). Those in the HFP were also significantly less likely than controls to be hospitalized within the past 4 months (OR=0.78, 95% CI: 0.69-0.88, p<0.001). Multivariate analyses indicated that CHF patients in the HFP were 95% less likely than controls to be admitted to the hospital during that period, independent of other risk factors for hospital admission.

Conclusion: Involvement by patients with CHF in a structured HFP at King Abdulaziz University in Jeddah, Kingdom of Saudi Arabia, is associated with significantly higher quality of life and lower likelihood of being hospitalized compared to CHF patients not involved.
Congestive heart failure (CHF) is a common chronic condition with an estimated 37.7 million cases worldwide. The prevalence of CHF in non-western countries such as Asia ranges from 0-6%. The mortality rate from CHF is high, with a 12-month incidence ranging from 34% in Africa to 23% in India, 15% in southeast Asia, 9% in South America, and 9% in the Middle East. Congestive heart failure makes up 1-2% of all hospitalizations in the United States of America and Europe, making it the most common cause of hospitalization. The cost to the healthcare system in the United States of America alone was $20.9 billion dollars in 2012 and is expected to rise to $53.1 billion dollars by the year 2030. In a study of CHF patients in England, the average cost per patient in the last 3 months of life was $11,508 (with estimates ranging from $10,895-12,119). Financial costs are particularly high due to recurrent hospitalization (accounting for more than 50% of annual costs). In the United States of America and Europe, 20-25% of CHF patients are re-admitted within 30 days of discharge. One early study found that families reported losing most or all their savings by the time the patient died.

To address frequent hospital re-admissions, high mortality, and the enormous costs, comprehensive HFPs have been developed to surround CHF patients with support, care, and close monitoring. These programs have been around since 1995, when a nurse-directed, multidisciplinary intervention was found to improve quality of life, reduce hospital use, and decrease medical costs. In a recent systematic review and meta-analysis of 47 clinical trials examining high-intensity home-visiting programs and multidisciplinary heart failure clinic interventions, researchers found that most programs enrolled persons with moderate-severe CHF with a median age of 70 years. These programs reduced all-cause 30-day hospital re-admission by 66% (RR=0.34, 95% CI: 0.19-0.62) for high intensity programs, although medium intensity programs had no significant effect. Across 9 studies, all-cause re-admission over 3-6 months was reduced by 25% and CHF-specific admission by nearly 50%.

In a second systematic review of the economic impact of HFPs (vs. usual care), researchers identified 34 studies: 51% reported HFP more effective and less costly; an additional 25% reported programs were more effective but not less costly; 14% reported no difference in benefit or costs; and the remainder reported no significant benefit but less cost (3%) or no significant benefit but more cost (6%). A third review examined 20 clinical trials testing the efficacy of transitional care programs for CHF, finding these programs increased patients' quality of life, decreased re-admissions, and decreased overall cost.

With regard to quality of life (QOL), CHF is a difficult condition to live with, especially in the advanced stages. Patients have difficulty coping with the functional disability and distressing physical symptoms caused by this condition. Quality of life is often severely compromised, given that fatigue, breathlessness and angina are uncomfortable and disabling. Not surprisingly, rates of anxiety and depression range from 30-60% in patients with CHF. Poor QOL due to CHF symptoms and frequent hospitalizations is also characteristic of patients with CHF in the Kingdom of Saudi Arabia. The prevalence of CHF in the Kingdom of Saudi Arabia ranges from 5.2-6.0/1000 in males and is 4.2/1000 in females. Among Saudis over age 65, the prevalence is 25.2/1000 (over 250% that reported in the United States of America), with ischemic heart disease, hypertension, and dilated cardiomyopathy the predominant causes. The expense on both the health care system and the family is high during hospital admission, which is frequent in these patients and often includes intensive care unit (ICU) transfers, long hospital stays, nosocomial infections, and increased mortality. One study found that the total cost of procedures, hospitalization, and early re-admission from diagnosis until death for Saudi CHF patients with reduced ejection fraction was $37,355 (SD=$49,336).

The aims of this study were to: compare the quality of life in CHF patients enrolled in a structured heart failure program (cases) with a waitlisted control group of CHF patients receiving usual care; and compare hospital admission rates within the past 4 months between cases and controls.

**Methods.** Searches were conducted using PubMed and Google Scholar to identify research related to the topic, particularly over the past 5 years. Primary search terms were congestive heart failure, heart failure programs, and quality of life.

This study, using an ex-post-facto comparative cross-sectional design, recruited a convenience sample of 80 patients with CHF. Patients involved in the King Abdulaziz University Hospital HFP in Jeddah,

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Kingdom of Saudi Arabia, for at least 4 months were identified (n=40) and compared to CHF patients on a waitlist (n=40). Inclusion criteria were: ages 18-85; a diagnosis of CHF (New York Heart Association [NYHA] classes I-IV); able to communicate without significant difficulty; and physically able to complete a 30-minute written questionnaire. Participants were excluded if they had a major psychiatric disorder with psychosis or a history thereof. Cases were not matched to controls.

Between January-June 2017, a trained research aide recruited patients meeting inclusion criteria from the heart failure outpatient clinic or inpatient services of the Division of Cardiology, Department of Medicine, King Abdulaziz University Hospital in Jeddah, Kingdom of Saudi Arabia, after receiving approval by their cardiologist to participate in the study. After completing and signing a statement of informed consent, participants were screened for eligibility criteria and then self-administered the study questionnaire. The study was approved by the institutional review board (IRB) of King Abdulaziz University in Jeddah, Kingdom of Saudi Arabia (No. 199-16). This study was conducted according to the principles of the Helsinki Declaration.

**Structured HFP** The HFP involves: a dedicated heart failure team; short messaging service (SMS) outreach texting; easy access of patients to service; patient education during “awareness days”; outreach calls to identify early warning symptoms; and medication support. The HFP mobilizes a team of professionals that surround the patient, providing monitoring and support.

The patient is first evaluated by a heart failure consultant who determines the etiology of CHF and risk factors. Next, the patient’s clinical condition is evaluated by measuring systolic and diastolic blood pressure, heart rate, electrolytes, renal and thyroid function, and vitamin levels. Next, symptoms of volume overload based on NYHA classification are determined, along with risk factors such as cardiac ischemia, hypoglycemia/hyperglycemia, and palpitations. A clinical pharmacist then reviews the patient’s medications and makes recommendations to the clinician. Additional laboratory tests are performed as indicated including an echocardiogram, Holter monitor, electrocardiography (ECG), ambulatory blood pressure, cardiac Magnetic Resonance Imaging (MRI), and coronary computed tomography (CT) angiography. Patient education emphasizes the importance of sodium restriction, participating in physical activity (tailored to the patient’s condition), smoking cessation, medication compliance, and detection of warning signs such as shortness of breath, lower limb swelling, and increased body weight.

Patients with non-ischemic cardiomyopathy are referred to the electrophysiology service for implantation of an intra-cardiac defibrillator, or alternatively, cardiac resynchronization therapy if the ejection fraction (EF) is less than 35% or a left bundle branch block is present and the patient has been on optimum medication therapy for at least 4 months. Patients with ischemic cardiomyopathy have this carried out if their EF is less than 30% or in the presence of a left bundle branch block if the patient has been on optimum medical therapy for at least 3 months or is one month post percutaneous coronary interventions. An intracardiac defibrillator (ICD) is placed if the EF<30%, the QRS is narrow and the patient is in good physical condition.

The patient receives weekly appointments for the next 4-6 weeks, and then every 2 or 3 months thereafter depending on their condition. Between appointments, patients are called regularly on their mobile phones and a checklist is used to ensure they watch for early warning signs and are aware of accessibility to HFP staff. In addition, an “awareness” SMS text is sent concerning updates related to vaccination and risk factors such as smoking and diet. The patient can come to the hospital at any time if warning signs appear. Finally, the physician, clinical pharmacist and clinical educator must sign off to ensure they have completed their responsibilities.

**Standard care control group.** Those in the standard care group (controls) were patients on a waitlist to enter the HFP and received usual cardiac care. These individuals received regular appointments at intervals of 4-6 months, but had no open access to cardiac clinic staff, no special education, no clinical pharmacist evaluation, no heart failure specialist evaluation (other than their regular cardiologist), no outreach calls from HFP staff, no outreach educative SMS texts, and no collaboration with the electrophysiology service.

**Questionnaire.** Demographics examined were age (years), gender, nationality (Saudi vs. non-Saudi resident), education (years), employment status (employed vs. not employed), annual income, and marital status (married vs. other). Religiosity was assessed using the 13-item Muslim religiosity scale (MRS), (specific religion; however, was not assessed in the questionnaire).19

The he patient health questionnaire-9 (PHQ-9) assessed depressive symptoms.20 The PHQ-9 is a widely used measure for identifying depressive symptoms and has excellent psychometric properties in medical
and psychiatric patients. The PHQ-9 incorporates Diagnostic and Statistical Manual of Mental Disorders, 4th version diagnostic criteria for major and minor depressive disorder, assessing the presence, severity, and duration of the 9 primary symptoms of major depression. Total scores of 10 or higher have a sensitivity and specificity of 88% for major depression; scores of 5 represents mild, 10 moderate, 15 moderately severe, and 20 severe depression.

Anxiety symptoms were measured using the 7-item generalized anxiety disorder scale (GAD-7). The GAD-7 measures severity of anxiety symptoms experienced during the past 2 weeks on a scale from 0 (not at all) to 3 (nearly every day), with scores ranging 0-21, with Mild scores 5, moderate scores 10 and severe anxiety scores 15. The GAD-7 has a sensitivity of 89% and a specificity of 82% for detecting significant symptoms of generalized anxiety and other anxiety disorders. Like the PHQ-9, the GAD-7 is widely used in primary care settings. The psychometric properties of the scale are well-established and internal reliability is high (α=0.91).

The primary outcomes examined in this study were QOL and hospital admission. Heart failure specific QOL was assessed with the Minnesota living with heart failure questionnaire (LIhFE). The LIhFE is a 21-item scale that measures the physical, emotional, social and psychological dimensions of QOL that are likely impacted by heart failure. Test-retest reliability is high (r=0.87), as is internal reliability (α=0.92). The LIhFE is a relatively brief psychometrically reliable and valid measure of QOL used in many heart failure studies. Higher scores indicate worse QOL.

Number hospital admissions (all-cause) during the 4-month period prior to the evaluation was assessed by retrospective patient self-report and confirmed by review of the patient’s medical record. Other heart failure characteristics assessed were NYHA heart failure class and duration of heart failure (years). Cigarette smoking was also asked about. The primary predictor of QOL and frequency of hospital admission was months spent in King Abdulaziz University’s heart failure program (and a secondary predictor was being in the HF program vs. control group).

**Statistical analyses.** Descriptive statistics were used to calculate variable medians, ranges, percentages and counts. Since most continuous and ordinal variables in this study were non-normally distributed, they were dichotomized at the median and chi-square statistic used to examine differences between cases and controls on demographic, social/cultural, psychological, and health characteristics (Table 1). Power analyses indicated that a total sample of 80 (40 in each group) was needed for a >80% power to detect a moderately large effect size (Cohen's d=0.65) at a probability level of 0.05 for a 2-tailed test (assuming a pooled standard deviation of 1.1 for the QOL score). The primary hypotheses related to QOL and hospital admissions, controlling for other correlates, were tested using a series of 4 logistic regression models for each outcome (Tables 2 and 3). We chose number of months in the HFP (rather than those in the HF program vs. controls) as the primary predictor because it would be a better indicator of HFP exposure (range 4-14 months for cases, 0 for controls). First, the primary predictor (months in HFP) was entered into the model (Model 1), then demographic and social/cultural characteristics (Model 2), then psychological factors (depression and anxiety in the model with QOL as the dependent variable; depression, anxiety, and QOL in the model predicting days hospitalized) (Model 3), and finally heart failure characteristics (NYHA class, duration of CHF and smoking status (Model 4). In order to minimize the number of variables included in each model due to the small sample size, only predictors significant at an α<0.15 were carried forward from one model to the next, and the final model (Model 4) included only those variables significant at α<0.10. Level of statistical significance was set at α=0.05 and was not adjusted for multiple comparisons given the exploratory nature of these analyses. Statistical analyses were performed using SAS (version 9.4; SAS Institute Inc., Cary, North Carolina).

**Results.** All 80 participants who were approached completed the questionnaire (40 cases and 40 controls). Cases and controls were not significantly different with regard to age, gender, education, nationality, employment status, income, marital status, religiosity, or heart failure/health characteristics (Table 1).

**Quality of life.** Bivariate analyses indicated that those in the HFP were significantly less likely to score above the median on heart failure specific QOL (35.0% vs. 60.0%, p=0.025) (Table 1). In multivariate analyses, time spent in the HFP was significantly and independently related to QOL (OR=0.83, 95% CI: 0.82-0.95, p=0.007) after controlling for anxiety symptoms, NYHA class, and duration of CHF (Table 2). Given the large increase in the likelihood ratio χ² when anxiety symptoms were added in Model 3 (from 3.8 to 14.1) and further increase when NYHA was added in Model 4 (from 14.1 to 39.4), these may be considered intermediate factors or the mechanism through which the HF program may improve QOL. Exploratory analyses indicated that when the cases vs. controls was used as the primary predictor (instead of months in the program), results were similar (OR=0.11, 95%
CI: 0.02-0.50, \( p = 0.005 \) indicating nearly a 90% lower likelihood of scoring above the median on poor QOL among those in the HFP (analyses not shown).

Hospital admission. Bivariate analyses indicated that the likelihood of being admitted to the hospital in the past 4 months (one or more times) was significantly lower among cases in the HFP compared to controls (27.5% vs. 85.0%, \( p < 0.001 \)) (Table 1). The likelihood of being admitted more than once during the past 4 months was also lower in cases than in controls (10.0% vs. 32.5%, \( p = 0.014 \)).

In multivariate analyses, months spent in the HFP were associated with a lower likelihood of being admitted to the hospital in the past 4 months (OR=0.78, 95% CI: 0.69-0.88, \( p < 0.001 \)), independent of other predictors (age and duration of CHF) (Table 3). In exploratory analyses, when case vs. control status was entered into

| Characteristics | Cases | Controls | \( P \)-value |
|-----------------|-------|----------|--------------|
| **Demographics/Social characteristics** |
| Age (>60 years) (median) | 21 (52.5) | 16 (40.0) | 0.262 |
| Gender (female) | 12 (30.0) | 11 (27.5) | 0.805 |
| Education (>12 years) (median) | 18 (45.0) | 21 (52.5) | 0.502 |
| Nationality (Saudi) | 5 (12.5) | 10 (25.0) | 0.152 |
| Employment status (employed) | 13 (33.3) | 15 (37.5) | 0.701 |
| Income (>10,000 SAR) (median) | 12 (30.0) | 8 (20.0) | 0.302 |
| Married (married) | 36 (90.0) | 33 (82.5) | 0.330 |
| Religiosity (MRS>median, 50.0) | 21 (52.5) | 15 (37.5) | 0.178 |
| **Psychological characteristics** |
| Depressive symptoms (PHQ-9>9.0) (median) | 14 (35.0) | 24 (60.0) | 0.025 |
| Anxiety symptoms (GAD-7>8.0) (median) | 10 (25.0) | 23 (57.5) | 0.003 |
| QOL (LIhFE>37.0) (median) | 14 (35.0) | 24 (60.0) | 0.025 |
| **Heart failure/Health characteristics** |
| Duration in heart failure program (median) | 11.0 months | - | - |
| Duration of heart failure (years >5.5) (median) | 18 (45.0) | 22 (55.0) | 0.371 |
| NYHA classification (III or IV) | 20 (50.0) | 16 (40.0) | 0.369 |
| Smoking status (yes) | 3 (7.7) | 2 (5.0) | 0.316 |
| **Frequency of hospital admission** |
| One or more admissions in past 4 months | 11 (27.5) | 34 (85.0) | <0.001 |
| Two or more admissions in past 4 months | 4 (10.0) | 13 (32.5) | 0.014 |

Values are presented as numbers and percentage (%). MRS - muslim religiosity scale, PHQ-9 - patient health questionnaire-9, GAD-7 - generalized anxiety disorder-7, QOL - quality of life, LIhFE - Minnesota living with heart failure questionnaire (lower scores indicate higher QOL), NYHA - New York heart association. Differences between cases and controls were assessed using the chi-square statistic.

**Table 1 -** Comparison of cases and controls (n=40).

**Table 2 - Multivariate predictors of quality of life (scores above the median, indicating poor QOL).**
Model 4 instead of months in the HFP, the results were similar (OR=0.05, 95% CI: 0.01-0.19, \( p < 0.001 \), controlling for gender, QOL, and duration of CHF) (analyses not shown). In other words, CHF patients in the program were 95% less likely than controls to have been hospitalized in the past 4 months.

**Discussion.** In this study, we examined the effects of a structured heart failure program on quality of life and frequency of hospital admission among patients with CHF. Those in the HFP scored significantly better on heart failure specific QOL and were much less likely than wait-listed controls (95%) to have been admitted to the hospital in the previous 4 months.

Heart failure programs are now starting all over the world. In Germany, a randomized clinical trial examined the effects of intensive case management on CHF outcomes among 1202 cases compared to controls. Those in the intervention group had a reduced rate of hospital admission/re-admission (6.2%/18.9% vs. 16.6%/36.0%). However, there was no significant difference in mortality, length of hospital stay, or costs per hospital stay. Nevertheless, the average annual costs for inpatient treatment in the intervention group were over two-thirds lower (67.5%) than those in the control group. Thus, the general consensus around the world is that intensive HFPs impact re-admissions, costs of care, mortality in many studies, and quality of life.

Our review of the literature uncovered only 2 studies from Kingdom of Saudi Arabia that have examined the effects of HFPs on outcomes in CHF patients. In the first study, investigators conducted a retrospective chart review of 413 patients admitted with CHF between 2008-2009 to King Abdulaziz Medical City in Riyadh, Kingdom of Saudi Arabia. All admitted patients were asked to participate in a nurse-led HFP, with 199 agreeing and 214 choosing usual care. The only outcome examined was all-cause mortality. The HFP involved support from a team consisting of a nurse specialist, cardiac diabetic nurse, cardiac rehab nurse, and dietitian. Participants after discharge were followed every 3 days up to 3 months depending on their clinical condition. Results indicated a reduction in all-cause mortality (HR=0.40, 95% CI: 0.20-0.80).

In the second study, researchers approached 197 patients with CHF soon after admission to King Abdullah Medical City in Jeddah, Kingdom of Saudi Arabia, non-randomly assigning 121 to a HFP and 76 to a usual care group. Outcomes examined were length of index stay, in-house mortality, and one-year re-admission rate. The HFP consisted of a 4-day clinical pathway during hospitalization that involved careful monitoring and completion of a daily checklist by a nurse coordinator (which included patient education), a 72-hour post-discharge telephone call, and early post-discharge appointments with a cardiac nurse specialist and cardiologist. Results indicated a reduction in index hospital stay (7.6 vs. 11.1 days, \( p < 0.002 \)), in-house mortality (1.6% vs. 7.8%, \( p = 0.03 \)), and one-year re-admission rate (36% vs. 57%, \( p < 0.003 \)).

The results of both studies above are consistent with those from the current study, supporting the effectiveness of structured HFPs in the reduction of hospital re-admission and mortality, although neither of the other studies examined the programs’ effects on QOL. We were unable to identify any other studies that examined the effect of HFPs on QOL in Kingdom of Saudi Arabia.

### Table 3 - Multivariate predictors of one or more hospital admissions over past 4 months.

| Characteristics | Model 1 OR (95% CI) | Model 2 OR (95% CI) | Model 3 OR (95% CI) | Model 4 OR (95% CI) | \( \chi^2 \), n(%) |
|-----------------|-------------------|-------------------|-------------------|-------------------|-------------|
| Duration in HF program | 0.81 (0.73-0.89) \(< 0.001 \) | 0.77 (0.68-0.86) \(< 0.001 \) | 0.77 (0.68-0.86) \(< 0.001 \) | 0.78 (0.69-0.88) \(< 0.001 \) | 80 (23.6) \(< 0.001 \) |
| Demographics/Social | Age --- --- 0.93 (0.88-0.99) \( p = 0.017 \) | Gender (female) --- --- 3.92 (1.02-15.0) \( p = 0.047 \) | --- --- --- --- --- --- --- --- --- |
| HF/Health | Duration of HF (years) --- --- --- --- --- --- 1.23 (1.06-1.44) \( p = 0.009 \) | Likelihood ratio \( \chi^2 \), n(%) 80 (23.6) \(< 0.001 \) 80 (35.2) \(< 0.001 \) 80 (35.2) \(< 0.001 \) 80 (40.5) \(< 0.001 \) |

--- indicates \( p > 0.15 \) for variable when included in model; final models include only those variables associated with the outcome at \( p < 0.10 \) (except duration in HF program, which was included in all models).

Age, gender, education, nationality, employment status, income, marital status, religiosity, depressive symptoms, NYHA class and smoking status were not related to QOL in any of the models at \( p < 0.15 \) and so were not included in the table above.
of Saudi Arabia. Not only was QOL better among patients in our HFP, but both depressive symptoms and anxiety symptoms were significantly lower compared to controls. In studies outside of the Kingdom of Saudi Arabia, depression is known to predict greater use of health services, worse health outcomes, and greater mortality.26,27

Heart failure programs appear to benefit patients by providing emotional support, encouraging self-care activities, and increasing regular monitoring, which may detect problems at an early stage when they are treatable. Poor QOL, often manifested by increased depression and anxiety symptoms, can negatively affect cardiac rehabilitation and contribute to difficulties and delays in returning to normal activity.28 Negative emotions have long been known to increase the risk of further heart damage, which may then contribute to the development or worsening of heart failure.29 Major depression is a strong predictor of a second Myocardial Infarction, angioplasty, and coronary bypass surgery after myocardial infarction, and as noted above, predicts increased mortality in patients with heart failure.30

Providing emotional support to patients with CHF after acute hospitalization, like that provided in HFPs, has been shown to improve health outcomes.30,31

Limitations. Several limitations affect results of the present study. First, this was not a randomized clinical trial, but rather a comparison of convenience samples of cases in the HFP and controls waiting to be enrolled in the program. Second, those administering the questionnaire were not blind to treatment group (they knew who was in the HFP and in the control group), although all aspects of the questionnaire were self-reported by patients themselves. Third, we did not inquire about physical comorbidities, medications, echocardiography findings, or psychiatric disorders other than depression and anxiety, factors that could influence quality of life and the results of this study. Fourth, in conducting the power analysis we assumed a pool standard deviation of 1.0 for QOL, which was far below what was found here (25.0); this also suggests that QOL scores were not normally distributed. Finally, cases and controls in this study were not intentionally matched with each other; however, no differences were found between groups on any of the demographic or heart failure/health characteristics assessed here. Thus, based on these limitations, it is unclear what biases may have favored patients in the HFP.

On the other hand, the study also has a number of strengths. First, QOL, depressive symptoms, anxiety symptoms, and religiosity were all rigorously assessed using psychometrically valid measures, all of which are commonly used in medical patients. Second, multivariate analyses carefully controlled for other factors that might explain the relationship between HFP involvement and the outcomes reported here.

In conclusion, the current study provides evidence that structured HFPs can make a real difference in terms of the CHF patient’s quality of life and need for hospital admission in the Kingdom of Saudi Arabia. The present study found both significantly higher quality of life (along with fewer depressive and anxiety symptoms) and dramatically fewer hospital admissions in the past 4 months among those in the HFP (95% lower than for control patients). These findings indicate the need for future research, especially prospective studies and randomized clinical trials, to examine the efficacy of HFPs compared to usual care in improving mental health, reducing hospital admissions, and increasing longevity of patients with CHF in the Kingdom of Saudi Arabia and the rest of the Middle East.

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