

International Journal of Cardiology Sciences



ISSN Print: 2664-9020
ISSN Online: 2664-9039
Impact Factor: RJIF 5.42
IJCS 2024; 6(2): 24-29
www.cardiologyjournals.net
Received: 15-05-2024
Accepted: 23-06-2024

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Unmet needs in patients with acute HF med-delta acute HF registry

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DOI: <https://doi.org/10.33545/26649020.2024.v6.i2a.60>

Abstract

Background: Several treatments have been tested in acute heart failure (HF) patients, hitting different central pathogenic mechanisms; however, for now none of such mechanisms have been proved to effectively ameliorate mortality and rehospitalization of HF. This registry aimed to determine patient characteristics, practice patterns and outcome of cases with acute HF with decreased EF in the Med-Delta region using registry design and find if there is a gap between the result found in the registry and the recent guidelines and implanting a medical program to improve patients' wellbeing.

Methods: This prospective cohort study was conducted on 500 HF patients aged 30 or more presenting to the emergency department with manifestations of HF. The included had EF of 40% or less and NYHA classification ranging from II to IV. The patients were included regardless of any associating risk factors such as diabetes DM, hypertension, IHD, cerebrovascular accident, malignancy, AF, smoking, or COPD.

Results: All the associations were statistically significant for increasing the risk of HF rehospitalization except for gender, residency, and smoking. Furthermore, diabetes, ischemic heart diseases, and AF were highly statistically significant (P-value <0.0001). A significant association was detected between the NYHA classification of the included sample of patients and rehospitalization ($\chi^2= 61.3$; df= 2; P-value <0.0001).

Conclusions: There are statistically significant associations between the increased risk of HF rehospitalization and Hypertension, Cerebrovascular accident, COPD and Malignancy. Whereas there are highly significant associations with DM, Ischemic heart disease and AF and there were no statistically significant associations with gender, residency, and smoking. Our results strengthen the data in literature.

Keywords: Heart failure, registry, hospitalization

Introduction

Heart failure (HF) represents the end stage of the vast majority of cardiovascular disorders, it is still considered a crucial leading cause of mortality and morbidity globally ^[1], in the recent decades, incredible advance has been achieved in particular in the therapeutic treatment of chronic HF with reduced ejection fraction (HFrEF) with disease-modifying medications that can improve the functions, morbidity as well as survival ^[2].

Several treatments have been evaluated in acute HF cases, hitting different central pathogenic mechanisms; however, for now none of such mechanisms have been proved to effectively ameliorate mortality and rehospitalization of patients with HF ^[3].

mercifully, good therapeutic options are available for cases suffering chronic HF with left ventricle rEF ^[4]. Disease-modifying therapeutic agents include angiotensin-converting enzyme (ACE) inhibitors, β -blockers, mineralocorticoid receptor blockers, heart resynchronization treatment and the newly getting commercialized sacubitril/valsartan revealed good impacts on exercise ability in addition to improving quality of life (QOL) and decreasing the rate of hospitalization and mortality ^[2, 5].

The query is how to improve the application of HF guidelines. One of the accepted options is to include cases with HF in a multidisciplinary disease management program (DMP). This suggestion was validated as a class I recommendation in international HF guidelines for >10 y ^[6] for its effect on reducing hospitalization and mortality ^[7].

The requirement of this program are not new; one of the articles of the American Journal of Public Health in 1960 titled "CHF, the patients and their community", Raymond T. Benack actually put the broad lines of a disease management program for chronic HF^[8]. The paper posed enormous numbers of cases, with complicated condition along with poor prognosis and suggested a multidisciplinary method as well. The same rule was described for nurses including home visits as well^[8].

For Benack the principal benefits of the home-based nursing care for cases with HF is the reduced rate of hospitalization in addition to the early determination of events of HF deterioration. Hence, the conclusion was "by such combined services the patients can receive good home care, congestive HF recurrence will be reduced, and the community and the patient can have a financial saving via the reduction in readmission rate as well as the total hospitalization duration^[9]. Ultimately, of course, the QOL of the patients will improve as a result of preventing complications arise from the recurrence of CHF^[10]. The aim of the registry is to determine patient characteristics, practice patterns and outcome of patients with acute HFrEF in the Med-Delta region using registry design and find if there is a gap between the result found in the registry and the recent guidelines and implanting a medical program to improve patients' wellbeing.

Patients and Methods

This prospective cohort study was carried out on 500 HF cases aged 30 or more presenting to the emergency department with criteria of HF. The included had EF of 40% or less and NYHA classification ranging from II to IV. The patients were included regardless of any associating risk factors that include DM, hypertension, IHD, cerebrovascular accident, malignancy, atrial fibrillation (AF), smoking, or COPD. This study was conducted at the Mid Delta hospitals, namely Tanta university hospitals, Zefta-Jones general hospital, Shebein El-kom teaching hospitals, El-mataryah teaching hospitals, the national heart institute, and El-Mahala cardiology center for six months.

Informed consent was obtained from each patient and approval from the Ethical Committee was taken as well.

Exclusion criteria included patients with congenital heart diseases, patients aged less than 30, patients with mild HF symptoms, defined as NYHA classification I, patients with poor echogenicity, patients with intraventricular devices inserted and patients who did not consent for participation in our work.

Data collection

Following explaining the aim and expected steps of the study individually to the potential participants, consent was sought from patients eligible for participation in the sample. The data were collected utilizing interviews (face-to-face questions). The Patients were asked the following questions: 1. what is your age? 2. How do you classify your residency (rural or urban)? 3. Are you diabetic? 4. Are you hypertensive? 5. Have you experienced an event of ischemic heart disease? 6. Have you ever experienced a cerebrovascular accident? 7. Do you complain of palpitations/ are you diagnosed with AF? 8. Are you a smoker? 9. Are you treated for chronic obstructive pulmonary disease? 10. Do you have any oncological history?

On admission, all the study patients had the following

- 1. Full history taking:** All the patients had complete clinical history taking including: Personal history: Name, date of birth, residency, history of other chronic illnesses, and family history of hypertension, CAD.
- 2. Clinical/ physical examination:** Examination for any signs or symptoms of HF: lower limb edema, congestive HF (rales, pulmonary edema, etc.), congested neck veins, etc.
- 3. Resting 12-lead ECG.**
- 4. Full laboratory work-up:** Complete blood count, ABG, urea, serum creatinine, liver function testing, electrolyte levels (Sodium, potassium, and Mg), cardiac enzymes when needed based on the assessment of chest pain (Quantitative troponin and CK-MB).
- 5. Echocardiography:** Left ventricular function/ EF was assess by eyeballing at almost all possible echocardiographic view (long parasternal, short parasternal, and apical four, three, and two-chambre views), and that was confirmed by measuring the wall thickness/cavity by the M-mode during the systole and diastole.
- 6. Multidisciplinary team assessment:** All the patients were assessed by cardiology, urology, endocrinology, and nutrition internists for assessment of the overall complexity, end-organ damage, and the need for any additional management. This would guarantee a holistic approach and improvement of the patients' overall quality of life.

Follow-up: The study population were followed up for six months after discharge from the aforementioned hospitals through phone calls. The patients were asked about the improvement of their symptoms and their compliance with medical treatment, including any treatment prescribed by other specialties as a part of the multidisciplinary team management. Furthermore, before discharge, the participants were informed to inform the data collector whenever they would need any rehospitalization for recurrence of HF symptoms. Nonetheless, the patients were asked about any need for rehospitalization during the follow-up phone calls in order not to miss any data.

Statistical analysis

All analyses were conducted via IBM statistical package for Social Science (SPSS) version 23. The cut-off point for statistically significance result was set at $P \leq 0.05$. Continuous data were displayed as mean \pm SD, whereas frequency and percentage was used to present categorical data. Chi-square test was used to measure the correlation between having completed medical treatment, the individual risk factors, and the NYHA classification with rehospitalization. Linear regression was performed to assess the combined risk of diabetes, hypertension, IHD, AF, COPD, CVA, smoking, and compliance to treatment on rehospitalization.

Results

Thirty-seven percent (N=138) of participants were females, whereas 63% (315) were men. The mean age of participants was 59.27 ± 13.33 y, and the mean BMI of them was 25.09 ± 2.45 kg/m². Furthermore, the mean left ventricular EF was 25.85 ± 6.99 . According to the NYHA classification, 16.6% (N=83) of participants were NYHA class II, 39.6% (N=189)

were NYHA class III, and 43.8% (N=219) were NYHA class IV. Table1 displays the baseline characteristics and risk factors of patients.

Table 1: Demographic and baseline characteristics of the studied patients.

Characteristics	Participants (N=500)
Age (year)	59.27±13.33
BMI (kg/m ²)	25.09± 2.45
LVEF (%)	25.85± 6.99
Risk factors	N=500
DM	342 (68.4%)
Hypertension	263 (52.6%)
Ischemic heart disease	371 (74.2%)
Cerebrovascular accident	66 (13.2%)
AF	99 (19.8%)
Smoking	404 (80.8%)
COPD	32 (6.4%)
Malignancy	50 (10%)
Residency (rural)	198 (39.6%)

As the table 1 implies, all the associations were statistically significant for increasing the risk of HF rehospitalization

except for gender, residency, and smoking. These three insignificant risks were also weakly associated with rehospitalization risk. Furthermore, diabetes, ischemic heart diseases, and AF were highly statistically significant (P-value <0.0001). Regarding diabetes, there was a moderate relationship with the risk for rehospitalization (Cramer’s V 0.217), and those with no diabetes were 64% less likely to be rehospitalized (odds ratio 0.36). IHD showed also a moderate relationship (Cramer’s V 0.203), and again those with no IHD were 64% less likely to be rehospitalized (Odds ratio 0.36). AF, despite its high statistical significance, showed a weak relationship as a predisposing factor for rehospitalization in HF patients. Furthermore, the group with no AF was 2.57 more likely to be rehospitalized (Odds ratio= 2.57).

Hypertension, CVA, COPD, and malignancy were all statistically significant risks (P-value 0.004, 0.001, 0.003, and 0.02, respectively). Nonetheless, they had a weak association with rehospitalization risk.

Linear regression of diabetes, hypertension, IHD, AF, COPD, CVA, smoking, and compliance to treatment was statistically significant. These risks were responsible for 65.5% of rehospitalization events (Adjusted R²=.655).

Table 2: The association between possible risks and rehospitalization, their significance, and their strength.

Risk factor	X ² / Chi-square test value	P-value	Cramer’s V	Odds ratio (No/yes)
DM	23.5	<0.0001	0.217	0.36
Hypertension	8.3	0.004	0.129	1.7
Ischemic heart disease	20.7	<0.0001	0.203	0.36
Cerebrovascular accident	10.5	0.001	0.145	2.65
AF	14.3	<0.0001	0.169	2.57
Smoking	0.706	0.401	0.038	1.21
Gender	1.34	0.25	0.052	1.24 (female/ male)
Residency	0.35	0.55	0.026	0.896 (rural/ urban)
COPD	9.1	0.003	0.135	4.03
Malignancy	5.17	0.02	0.102	2.12

Assessment of the association between being compliant on the medical treatment and the risk of rehospitalization was done via Chi-square test. The results of the Chi-square test of association showed a significant association between compliance on medications and rehospitalization ($\chi^2=313.4$; df= 1; P-value <0.0001). Cramer’s V was browsed to measure the strength of this association, and it showed a

very strong association between compliance on medical treatment and rehospitalization (Cramer’s V= 0.79). Furthermore, risk estimate analysis was also performed to assess the strength of association; this estimate revealed that those participants non-compliant on medications were a 90.9 times greater risk of rehospitalization for HF (odds ratio for compliance/ noncompliance= 0.011).

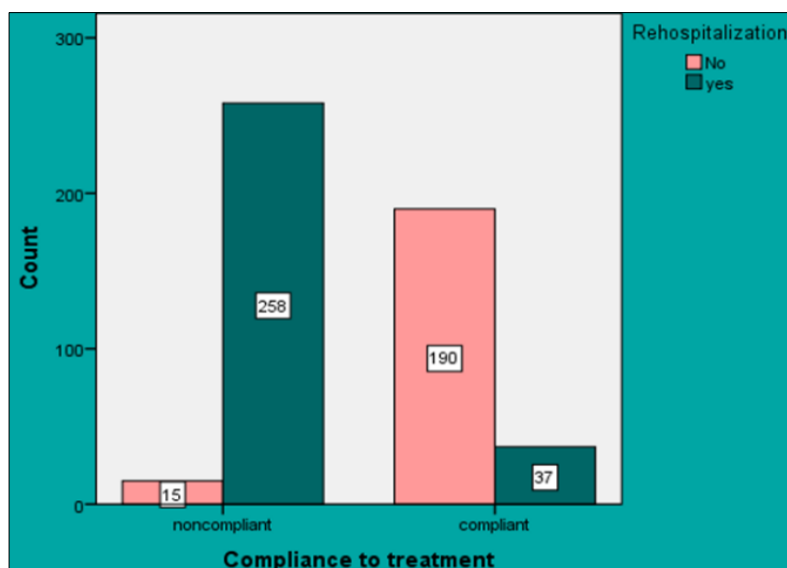


Fig 1: Bar chart of frequencies assessed by the Chi-square test for compliance on treatment and rehospitalization.

The association between NYHA classification and the risk of rehospitalization was done via Chi-square test. The result of the Chi-square test of association showed a significant association between the NYHA classification of the included sample of patients and rehospitalization ($\chi^2= 61.3$; $df= 2$; $P\text{-value} < 0.0001$). Cramer's V was tested to measure the strength of this association, and it showed a very strong relationship between the NYHA classification and rehospitalization (Cramer's $V= 0.35$); the more the NYHA classification, the more the risk of rehospitalization. It is worth stating that all the included participants had an NYHA classification from II to IV, and none had an NYHA classification of I (no symptoms with ordinary physical activity). Table 3 displays the number of patients per each category of NYHA classification.

Table 3: The number of patients rehospitalization per each category of NYHA classification and the total number of patients in each group. NYHA, New York heart association.

NYHA classification	Rehospitalisation	No Rehospitalisation	Total (N=500)
II	55	81	136
III	125	105	230
IV	115	19	134

Discussion

Consensus guidelines recommended using the term heart failure to refer to cases having established chronic HF with symptoms can be graded based on the NYHA functional classification [11, 12].

Regarding the possible risk factors, our results showed that 68.4% had been treated for DM. Furthermore, 52.6% were treated for hypertension, 74.2% had a history of IHD, 13.2% reported having a past cerebrovascular accident, and 19.8% reported known AF. Moreover, the participants had additional risk factors entailing smoking (80.8%), COPD (Chronic obstructive pulmonary disease; 6.4%, 32/500), and malignancy (10%).

We found several studies in literature that investigated cases with acute HF, [Lupon *et al.*, Buessler *et al.*, Chivite *et al.*, and Tromp *et al.*, [13-16]] these studies stated comparable values of LVEF and BMI with our results. Regarding the NYHA studies revealed that the majority of cases were functional class III & IV in agreement with our results.

In accordance with our results Tromp *et al.*, [16] reported that the potential risk factors that included hypertension, DM, history of smoking, and previous history of MI. Whereas hypertension was accompanied by a 3 fold increased risk of ongoing HF in young cases (hazard ratio 3.02, 95 percent, confidence interval 2.1 - 4.34), in comparison with a 1.4-fold increase in the risk amongst elderly cases (1.43, 1.13 - 1.81) additionally, DM, smoking, and history of MI cause increased risk amongst younger cases, while effect size amongst elderly cases was much less eminent for DM (hazard ratio: 3.86 (2.39 - 6.23) in young Vs. 1.66 (1.24 - 2.24) in elderly), smoking (2.58 (1.83- 3.63) Vs. 1.21 (0.8- 1.83)), and previous MI (3.3 (1.77- 6.14) versus 1.35 (0.89 to 2.08)). On the contrary, they didn't detect that age modified the correlation of BMI or increased body weight with ongoing HF. While population-based study by Jackson *et al.*, [17] reported the commonest comorbidity diagnosed in individuals primary hospitalized for heart failure were hypertension (72 percent), IHD (56 percent), DM (48 percent), CKD (47 percent), and AF (43 percent). In

addition, the mortalities with comorbid HF, the commonest underlying causes included IHD (44 percent), hypertension (21 percent), and COPD (21 percent).

The current work presented that the association between the risk factors and rehospitalization was measured individually using the Chi-square test. We found that all the associations were statistically significant for increasing the risk of HF rehospitalization except for gender, residency, and smoking. These three insignificant risks (gender, residency, and smoking) were also weakly associated with rehospitalization risk. Furthermore, diabetes, ischemic heart diseases, and AF were highly statistically significant ($P\text{-value} < 0.0001$). Regarding diabetes, there was a moderate relationship with the risk for rehospitalization (Cramer's $V 0.217$), and those with no diabetes were 64% less likely to be re-hospitalized (odds ratio 0.36). IHD showed also a moderate relationship (Cramer's $V 0.203$), and again those with no IHD were 64% less likely to be hospitalized (odds ratio 0.36). AF, despite its high statistical significance, showed a weak relationship as a predisposing factor for rehospitalization in HF patients. Furthermore, the group with no AF was 2.57 more likely to be hospitalized (odds ratio= 2.57). Hypertension, CVA, COPD, and malignancy were all statistically significant risks. Nonetheless, they had a weak association with rehospitalization risk. Linear regression of diabetes, hypertension, IHD, AF, COPD, CVA, smoking, and compliance to treatment was statistically significant. These risks were responsible for 65.5% of rehospitalization. Our assessment of the association between being compliant on the medical treatment and the risk of rehospitalization was done via the Chi-square test. The result of the Chi-square test of association showed a significant association between compliance on medications and rehospitalization. Cramer's V was browsed to measure the strength of this association, and it showed a very strong association between compliance on medical treatment and rehospitalization. Furthermore, risk estimate analysis was also performed to assess the strength of association; this estimate revealed that those participants non-compliant on medications were a 90.9 times greater risk of rehospitalization for HF.

Similarly, there was a significant association between the NYHA classification of the included cases and rehospitalization ($\chi^2= 61.3$; $df= 2$; $P\text{-value} < 0.0001$). Cramer's V was tested to measure the strength of this association, and it showed a very strong relationship between the NYHA classification and rehospitalization (Cramer's $V= 0.35$); the more the NYHA classification, the more the risk of rehospitalization. It is worth stating that all the included participants had an NYHA classification from II to IV, and none had an NYHA classification of I.

However, results Lupon *et al.*, [13] reported that there is highly significant correlation between the age, Diabetes, Renal insufficiency and Anaemia and primary endpoint of cardiac deaths or HF-related hospitalization. There was significantly decreased incidence for cardiovascular and HF-related repeated hospitalization in HF-recovered cases (1.6 & 0.68 / 10 person-years, respectively) in comparison with HF-rEF and HF-pEF. Nevertheless, in a sensitivity analysis, the difference between HF-recovered and HF-rEF patients was that cardiovascular hospitalization was commonly less in the HF-recovered group ($P = 0.006$). They analyzed 1598 cardiovascular hospitalization (787 HF-related) showed a clear reduced time-to-1st events as well as recurrent HF-related hospitalization in HF-recovered cases, in comparison

with HFpEF and HFrEF cases. Recurrent hospitalization is an increasing concern due to diagnosing HF is in ambulatory individuals, 83percent were hospitalized ≥ 1 time and 43percent ≥ 4 times.

Ponikowski *et al.*,^[2] reported the Guidelines of diagnosing and management of AHF and CHF, they concluded that when β -blocker medications were discontinued in individuals hospitalized with AHF was accompanied by significant increase in-hospital mortalities, short-term mortalities and the combined endpoint of short-term rehospitalizations or mortalities and they concluded that monitoring of pulmonary artery pressures via the use of a wireless implantable hemodynamic monitoring system (CardioMems) might be indicated in symptomatic cases suffering HF with history of hospitalizations due to HF to decrease the risk of rehospitalization. Also, Kurmani & Squire,^[11] reported that studies the prognosis for individuals hospitalized for acute HF is still bleak with rate of mortality or recurrent hospitalization at six months is about fifty percent.

Regarding rehospitalization the study by Zaprutko *et al.*,^[18] reported that 54% of cases (345 out of 641) with re-admission for any etiology ≥ 1 time and 46 percent with re-admission for ≥ 1 time during follow-up. The mean time from discharge to the 1st HF re-admission within one year was 137 ± 108 days. On the other hand, the thirty-day HF re-admission rates were 5percent, and, according to the length of index hospitalization duration, 5 percent of cases hospitalized for one to seven & eight to twenty-one days and 3 percent of cases hospitalized for 22 days or more were readmitted. In general, the median duration of the index hospitalization in re-hospitalized cases was 7 days (4–10) and didn't differ from the stay duration of those who weren't re-hospitalized (~12 months of FU; median 7 days, $p = 0.957$). The main limitation in this study was the sample size limitation; further variables and more sample size are needed for external validity and generalization of this study results. Furthermore, loss of follow-up with patients was another major limitation whether for unknown reasons or due to patient death. Management plan, including medical treatment and non-medical treatment, should be optimized for patients hospitalized for HF before their discharge from hospital to avoid recurrence and rehospitalizations. Multidisciplinary team approach should be activated whenever applicable for HF patients.

Conclusions

HF (HF) is still an essential main reason of morbidity and mortality all over the world. Acute HF was accompanied by significant increase in-hospital mortalities, short-term mortalities and the combined endpoint of short-term rehospitalizations or mortalities. We found that there are statistically significant associations between the increased risk of HF rehospitalization and Hypertension, Cerebrovascular accident, COPD and Malignancy. Whereas there are highly significant associations with DM, Ischemic heart disease and AF and there were no statistically significant associations with gender, residency, and smoking. Our results strengthen the data in literature.

Financial support and sponsorship: Nil

Conflict of Interest: Nil

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How to Cite This Article

Shabak MA, Abd-Elwahab Hamdy E, Elhefnawy SB, Khalfallah M. Unmet needs in patients with acute HF med-delta acute HF registry. *International Journal of Cardiology Sciences* 2024; 6(2): 24-29.

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