Assessment of Pharmacist Intervention Among Post Hospital Discharge Patients with Moderate and Severe Acute Heart Failure

Helen Faris Marzoog, **Manal Khalid Abdulridha,Shokry Faaz Nassir**
****Department of Clinical Pharmacy, College of Pharmacy, Kufa University, Iraq***
*****Department of Clinical Pharmacy, College of Pharmacy, Al-Mustansiriyah University, Iraq***
******Department of Internal medicine, College of Medicine, Babylon University, Iraq***

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Corresponding Author email:
pharm.mrdha@uomustansiriyah.edu.iq
orcid: https://orcid.org/0000-0002-5059-7963

Abstract:

Background: Acute heart failure is the most common cause for hospitalization and the third highest cause of hospital readmission with nearly quarter of patients being re hospitalized within 30 days after discharge. Implementation of Clinical pharmacists in coordinated inpatient care, discharge planning and outpatient care result in significant improvements in adverse drug events reduction, medication adherence, quality of life and patient knowledge.

Objective: Evaluating pharmacist- based program for patients with moderate and sever acute heart failure via improving summary discharge in reduction hospital readmission, enhancing medications adherence and improve quality of life.

Patients and Methods: This prospective study was carried out under interventional pharmacist- based program carried out on 50 patients whom completed this study, they were randomly allocated to two groups, program group who are receiving program for assessment and review starting from 30 minutes pre hospital discharge till 12 weeks. The control group on usual care which include physician-based discharge summary, routine laboratory test without pharmacist intervention (25 patients for each group).

Result: After 12 weeks of follow up among program patients in comparison with control group, study findings revealed significant improvement in self-care heart failure index domains (maintenance, management, confidence and total SCHFI score (P=0.001) in both moderate heart failure (NYHAIII) and severe heart failure (NYHAIV) groups, also increase in domains of belief medication questionnaire whether specific necessity and specific concern domains (P=0.001) or decreased in general harm and general overuse (P=0.001) in both moderate and severe heart failure. Moreover, increase in all domains of WHO quality of life questionnaire (WHOQOL) (P=0.001) in both moderate and sever heart failure with predominant improvement in moderate heart failure. Both serum brain natriuretic peptide (P=0.001) and cardiac troponin I (P<0.01) level were decreased in patients with moderate and severe HF and ejection fraction was improved (P=0.03) only among patients with severe HF of program group.

Conclusion: Implementing pharmacist- based management program for patients with moderate and severe acute heart failure via summary discharge markedly improve disease awareness, medication adherence, reduced hospital readmission and total mortality at the end-line of study among intervention patients compared to the usual care.

Key words: Role, Intervention, Clinical pharmacist, Acute heart failure, Readmission

تقييم تداخل الصيدلي للمرضى الخارجين من المستشفى الذين يعانون من قصور القلب الحاد المتوسط والشديد

هيلين فارس مرزوك، **منال خالد عبد الرضا، شكري فائز ناصر**
**فرع الصيدلة السريرية، كلية الصيدلة، جامعة الكوفة، العراق*
*** فرع الصيدلة السريرية، كلية الصيدلة، جامعة المستنصرية، العراق*
**** فرع الطب الباطني, كلية الطب، جامعة بابل، العراق*

الخلاصة:

الخلفية: قصور القلب الحاد هو السبب الأكثر شيوعًا لدخول المستشفى وثالث أعلى سبب لتكرار دخول المستشفى مع إعادة ربع المرضى تقريبا إلى المستشفى في غضون ٣٠ يومًا بعد الخروج من المستشفى. شمول الصيادلة السريريين في رعاية المرضى الداخليين وتهيئة خروجهم ورعاية المرضى الخارجيين يؤدي إلى تحسن كبير في تقليل الاثار الدوائية الضارة ,الالتزام بالأدوية , نوعية الحياة وتوعية المريض.

الهدف: تقييم البرنامج القائم على تداخل الصيدلي للمرضى الذين يعانون من قصور القلب الحاد المتوسط والشديد من خلال تحسين ملخصات الخروج في تقليل عدد مرات دخول المستشفى ، تعزيز الالتزام بالأدوية وتحسين نوعية الحياة للمرضى.

المرضى وطريقة العمل: أجريت هذه الدراسة والتي تضمنت برنامج يعتمد على تداخل الصيدلي على ٥٠ مريضا أكملوا هذه الدراسة حتى النهاية، تم تقسيمهم عشوائيا لمجموعتين، مجموعة البرنامج الذين يتلقون برنامج لتقييم الحالة ومراجعتها بدءا من ٣٠ دقيقة قبل خروجهم من المستشفى وحتى ١٢ أسبوعا بعد الخروج، والمجموعة الاخرى على الرعاية المعتادة بدون تداخل الصيدلي (٢٥ مريضا لكل مجموعة).

النتائج: بعد ١٢ أسبوعًا من المتابعة لمجموعة مرضى البرنامج مقارنةً بالمجموعة الاخرى، كشفت نتائج الدراسة عن تحسن كبير في مجال المحافظة، الادارة، الثقة والمعدل الكلي (p=٠,٠٠١) من استبيان مؤشر العناية الذاتية لفشل القلب في كل من قصور القلب المتوسط والشديد لمجموعة البرنامج، كذلك زيادة في مجال الضرورة والقلق حول استخدام الدواء ونقصان في مجال الاذى والافراط العام في استخدام الدواء (p=٠,٠٠١) من مجالات استبيان الاعتقاد بالدواء في كل من قصور القلب المتوسط والشديد لمجموعة البرنامج. فضلاً عن زيادة في جميع مجالات استبيان نوعية الحياة لمنظمة الصحة العالمية (WHOQOL) (P = ٠,٠٠١) في كل من قصور القلب المتوسط والشديد مع تحسن سائد في فشل القلب المتوسط. انخفاض مستوى كل من ال BNP (p=٠,٠٠١) و Troponin I (P<٠,٠١) في كل من قصور القلب المتوسط والشديد لمجموعة البرنامج مع تحسن مقدار ضخ القلب (p=٠,٠٣) لقصور القلب الشديد فقط من مجموعة البرنامج.

الاستنتاج: تنفيذ برنامج معالجة يستند إلى الصيدلي للمرضى الذين يعانون من قصور القلب الحاد المتوسط والشديد من خلال ملخصات الخروج يحسن و بشكل ملحوظ الوعي بالمرض، الالتزام بالأدوية وانخفاض تكرار دخول المستشفى والوفيات الكلية في نهاية الدراسة بين مجموعة مرضى برنامج التداخل الصيدلي مقارنة بمجموعة الرعاية المعتادة.

الكلمات المفتاحية:. دور، تداخل، الصيدلي السريري، فشل القلب الحاد، تكرار رقود المستشفى.

Introduction

Acute heart failure (AHF) includes both patients with typical presentation of heart failure signs and symptoms admitted for the first time and those patients with worsening of their preexisting cardiomyopathy (acute decompensated heart failure) [1]. It is most common cause for hospitalization and the third highest cause of hospital readmission, unplanned readmissions with nearly quarter of patients being re hospitalized within 30 days after discharge [2]. Despite therapeutic advancement, it is associated with poor prognosis and higher hospital mortality [3]. Acute heart failure an essential health problem in worldwide, with elevated prevalence in Asia more than western countries, ranging between 1.3 % and 6.7 % [4].

Patients have CVD, particularly with heart failure have complicated medication therapies, elevated prescription costs and multiple prescribers, at high risk for developing adverse drug reaction, and medication errors and poor adherence because of poly pharmacy, they also have greater usage of high-risk drugs such as anticoagulant agents so they are candidate for medication therapy management (MTM)[5,6]. The MTM is best accomplished by clinical pharmacist due to their knowledge of pharmacotherapy, understanding of insurance coverage, pharmacy benefit design and the convenience and accessibility of being able to talk to a pharmacist about medication [7].

Clinical pharmacists have taken their place to influence management of HF and direct patient care and its associated costs through self-management encourage, clinical information providing systems, decision support and community resources that result in significant improvements,

adverse drug events, medication adherence, quality of life and patient knowledge [8,9].

Implementation of clinical pharmacists in coordinated inpatient care, discharge planning and also as members health-care services for outpatient can play an important role in increasing patient education, improving dosing schedules and developing greater communication which are necessary ways to maximize patient adherence [10]

This prospective interventional study was designed to assess pharmacist–based management program for patients with acute heart failure using the experiences, skills and knowledge to provide adequate services to the health care team and patients. The principle elements of the program incorporate patient assessment and education combined with dietary recommendations aimed to improve summary discharge, reducing readmission of acute decompensation and finally the improvement in quality of patient's life

Materials and Methods:

This prospective interventional study enrolled 50 patients with acute heart failure admitted center for catheterization in Hilla/Iraq under supervision of interventional cardiologist. Scientific and Ethics Committee approved the protocol. Patient's oral and written consent was taken after full explanation of the aim of the study and ensure the reliability of the collected information. The patients were allocated into two groups: Program group included 25 patients receiving pharmacist-based program for assessment and review starting from 30 minutes pre hospital discharge, then during subsequent post hospital discharge visits 2, 4, 8, and 12weeks, and control group included 25 patients receiving usual care reviewed 30 minutes pre hospital discharge and 12 weeks post hospital discharge. The control patients were on usual medical care and follow up achieved by the medical staff only without pharmacist attachment. The patients assessment for both study group include heart failure discharge medication, Doctor Discharge Summary (DDS)[11], assessment of Self Care Heart Failure Index (SCHFI)[12], assessment of the patient adherence to the medications (Beliefs about medication questionnaire (BMQ)[13] , assessment of patients quality of life (WHOQOL-BREF) [14,15], in addition to monitoring heart rate, blood pressure, ejection fraction and laboratory test for BNP and Troponin I.

Statistical Analysis:

The results were presented as mean ± standard error (SE), fractions, or percentage of difference. All statistical analyses were accomplished via SPSS version 22.0 (SPSS, Inc.). Two sample t test was used for comparing the means of the two study groups baseline characteristics then data were analyzed by using of covariance analysis (ANCOVA) for this clinical study. Least Significant Difference (LSD) for pair-wise comparison between two groups. Accounting for the influence of the baseline levels as covariate to estimate adjusted end line, chi square test and correlation test were used accordingly when they were needed. The level of significance for all tests was estimated to be as: P-value ≤ 0.05.

Results:

The essential patients and disease characteristics of study groups was presented in Table (1)

Table (1): Essential patient and disease characteristics of the study groups

Essential Characteristics		Study arm				P value
		program		control		
		N	%	N	%	
Age(y) (mean±SD)		57±14.6		61.9±9.6		0.1 NS
Gender	Male	14.0	56%	16.0	64.0%	0.5 NS
	Female	11.0	44.0%	9.0	36.0%	
Associated diseases	Hypertension	13.0	52.0%	8.0	32.0%	0.1 NS
	Diabetes	7.0	28.0%	11.0	44.0%	0.2 NS
	IHD	12.0	48.0%	11.0	44.0%	0.7 NS
	Stroke	4.0	16.0%	5.0	20.0%	0.7 NS
Heart failure severity	NYHA III	19.0	76.0%	18.0	72.0%	0.7 NS
	NYHA IV	6.0	24.0%	7.0	28.0%	
Number of drugs	≤ 4 drugs	5.0	20.0%	7.0	28.0%	0.5 NS
	> 4 drugs	20.0	80.0%	18.0	72.0%	

Data presented as mean ± SD, Number of patients (n), Percentage (%),
Two sample *t*-test is used for statistical analysis of (age)
Chi square is used for statistical analysis of numerical parameters
NS: No significant differences (P>0.05).

Effect of the pharmacist-based program on Self Care Heart Failure Index (SCHFI) domains:

In both moderate heart failure (NYHAIII) and in severe heart failure (NYHAIV) groups, there was a highly significant improvement (P value ≤0.01) in maintenance, management and total SCHFI domains after 12 weeks of follow up among program patients in comparison with control group following adjustment of baseline means and significant improvement in confidence (P value≤0.05) in severe heart failure patients but not in patients with moderate heart failure

Table (2): Effect of the pharmacist-based program on SCHFI domains

SCHFI domain	NYHA class	Study arm	Estimated baseline	End line		*P* value	% of change
				Mean	SE		
Maintenance	NYHAIII	program	19.6	33.3	0.4	0.001**	69.8
		control		20.4	0.5		4.08
	NYHAIV	program	18.1	31.4	0.9	0.001**	73.4
		control		18.7	0.8		3.3
Management	NYHAIII	program	10.3	21.6	0.3	0.001**	109.7
		control		11.1	0.3		7.7
	NYHAIV	program	10.1	20.3	0.9	0.001**	100.9
		control		10.2	0.8		0.99
Confidence	NYHAIII	program	15.8	21.2	1.3	0.130	34.1
		control		18.1	1.4		14.5
	NYHAIV	program	15.9	20.7	1.5	0.019*	30.1
		control		14.7	1.4		-7.5
Total SCHFI	NYHAIII	program	46.2	70.4	0.8	0.001**	52.3
		control		50.4	0.9		9.0
	NYHAIV	program	42.6	70.2	1.185	0.001**	64.7
		control		43.6	1.715		2.3

Data presented as mean ± SE**,**
Data were analyzed by using the analysis of covariance (ANCOVA)
*P value ≤ 0.05 is considered significant
**P value≤ 0.01 is considered highly significant

Effect of the pharmacist-based program on Beliefs of Medication (BMQ) according to severity of heart failure:

In both moderate heart failure (NYHA=III) and severe heart failure(NYHA=IV) groups, and after adjustment of baseline means for program and control study groups there was ahighly significant improvement (Pvalue≤0.01)in specific necessity, specific concerns, general harm, general overuse,after12weeks of follow up among program patients in comparison with control group. The total BMQ score revealed no difference between study groups according to disease severity.

Table (3): Effect of the pharmacist-based program on Beliefs of Medication Questionnaire:

BMQ Domains	NYHA class	Study arm	Estimated baseline	End line		P value	% of change
				mean	SE		
Specific necessity	NYHAIII	program	12.3	19.0	0.5	0.001**	54.4
		control		15.4	0.5		25.2
	NYHAIV	program	12.8	21.6	0.7	0.001**	68.7
		control		16.5	0.7		28.9
Specific concerns	NYHAIII	program	11.5	18.8	0.4	0.001**	63.4
		control		13.0	0.4		13.0
	NYHAIV	program	11.2	18.4	0.9	0.001**	64.2
		control		12.6	0.8		12.5
General harm	NYHAIII	program	12.7	7.5	0.3	0.001**	-40.9
		control		12.3	0.3		-3.1
	NYHAIV	program	12.7	7.7	0.6	0.001**	-39.3
		control		12.6	0.5		-0.78
General overuse	NYHAIII	program	13.9	9.7	0.3	0.001**	-30.2
		control		13.1	0.3		-5.7
	NYHAIV	program	12.7	9.0	0.5	0.001**	-29.1
		control		13.0	0.4		2.3
Total Score	NYHAIII	program	50.4	54.8	0.6	0.535NS	8.7
		control		54.2	0.7		7.5
	NYHAIV	program	49.3	56.9	1.0	0.185NS	15.4
		Control		54.9	0.9		11.3

Data presented as mean ± SE**,**
Data were analyzed by using the analysis of covariance (ANCOVA)
NS= No significant differences (P value>0.05)
**(Pvalue≤0.01)is considered highly significant
BMQ: belief of medication questionnaire, NYHA: New York Heart Association,

Effect of the pharmacist-based program on Quality of Life:

After adjustment of baseline means for program and control groups, patients with both moderate heart failure(NYHA=III) severe heart failure(NYHA=IV), presented with highly significant improvement (P value≤ 0.01) in physical, psychological, social, environmental QOL domains, general perceptive QOL and total score of QOL after12weeks of follow up among program patients in comparison with

control group and the predominant improvement in QOL was noticed in patients with patients with moderate heart failure.

Table (4): Effect of the pharmacist-based program on quality of life:

QOL domain	NYHA class	Study arm	Estimated baseline	Endline		P value	% of change
				mean	SE		
Physical	NYHAIII	Program	34.4	62.9	1.7	0.001**	82.8
		Control		36.3	1.8		5.5
	NYHAIV	Program	29.6	50.6	4.3	0.03*	70.9
		Control		34.6	3.9		16.8
Psychological	NYHAIII	Program	42.0	69.0	1.4	0.001**	64.2
		Control		41.7	1.4		-0.7
	NYHAIV	Program	36.5	60.0	3.0	0.001**	64.3
		Control		39.9	2.8		9.3
Social	NYHAIII	Program	56.1	71.7	2.1	0.001**	27.8
		Control		55.7	2.1		-0.7
	NYHAIV	Program	53.2	76.1	3.3	0.003**	43.0
		Control		56.1	3.0		5.4
Environmental	NYHAIII	Program	58.0	80.3	1.5	0.001**	38.4
		Control		58.4	1.5		0.6
	NYHAIV	Program	58.1	73.3	2.7	0.004**	26.1
		Control		59.1	2.5		1.7
General perceptive	NYHAIII	Program	37.1	69.6	3.5	0.001**	87.6
		Control		41.0	3.6		10.5
	NYHAIV	Program	20.1	37.3	7.3	0.02**	85.5
		Control		17.9	6.8		-10.9
Total score QOL	NYHAIII	Program	47.6	68.1	1.2	0.001**	43.0
		Control		43.9	1.3		-7.7
	NYHAIV	Program	47.3	63.2	2.3	0.001**	33.6
		Control		41.2	2.1		-12.8

Data presented as mean ± SE**,**

Data were analyzed by using the analysis of covariance (ANCOVA)

*P value≤ 0.05 is considered significant

**P value ≤0.01 is considered highly significant

Effect of the pharmacist-based program on laboratory and clinical parameters:

After adjustment of baseline means for program and control arms, there was a highly significant decrease (Pvalue≤0.01) in BNP and troponin serum levels among program patients with moderate (NYHA=III) and severe (NYHA=IV) heart failure, no significant change in DBP and HR, meanwhile significant decrease in SBP (P value≤ 0.05) among program patients with severe heart failure. Also, the ejection fraction was significantly increased (P value≤ 0.05) among program patients with severe heart failure, after12weeks of follow up, in comparison to control group (P value≤ 0.05)

Table (5): Effect of the pharmacist-based program on laboratory and clinical parameters:

Parameter	NYHA class	Study arm	Estimated baseline	End line		P value	% of change
				Mean	SE		
BNP pg/ml	NYHAIII	Program	376.8	259.7	9.7	0.001**	-31.0
		Control		347.5	10.1		-7.7
	NYHAIV	Program	391.9	249.7	17.9	0.002**	-36.2
		Control		357.8	16.4		-8.7
TroponinI ng/ml	NYHAIII	Program	0.8	0.4	0.02	0.001**	-50.0
		Control		0.6	0.02		-25.0
	NYHAIV	Program	0.8	0.5	0.04	0.01**	-37.5
		Control		0.7	0.04		-12.5
SBP mmHg	NYHAIII	Program	121.6	111.8	3.3	0.4 NS	-8.0
		Control		115.8	3.4		-4.7
	NYHAIV	Program	118.4	100.3	6.5	0.05*	-15.2
		Control		113.9	6.0		-3.8
DBP mmHg	NYHAIII	Program	77.5	75.4	2.2	0.1 NS	-2.7
		Control		73.7	2.3		-4.9
	NYHAIV	Program	71.5	69.3	4.7	0.6NS	-3.0
		Control		66.2	4.3		-7.4
HR bpm	NYHAIII	Program	71.2	71.4	1.4	0.6NS	0.3
		Control		70.5	1.5		-0.9
	NYHAIV	Program	70.5	69.9	3.6	0.8NS	-0.8
		Control		68.6	3.4		-2.6
EF%	NYHAIII	Program	32.6	33.6	0.4	0.07NS	3.0
		Control		32.2	0.5		-1.2
	NYHAIV	Program	25.4	26.6	0.7	0.03*	4.7
		Control		23.9	0.7		-5.9

Data presented as mean ± SE

Data were analyzed by using the analysis of covariance (ANCOVA)

NS=No significant differences (*P* value>0.05)

*P value≤ 0.05 is considered significant

**P value ≤0.01 is considered highly significant

Discussion:

Cost and avoidable hospital readmission especially 30-day readmission were prevented by several effective interventional pathways that target patients who are more likely to benefit with ensuring the patients' safety and minimize the risks of relapse [16].

In the current study, the pharmacist- based program was carried on 25 of a total of 50 adult patients with a mean age of 59.4±12.5 years whom were readmitted to hospital with AHF with high prevalence among male patients though female patients has higher (30) day readmission

and mortality rate as stated by Mouaz et al.(2019)[17], those essential characteristics were matched to previous studies[18 ,19 ,20]. Study patients hospitalized with AHF were diagnosed as NYHAIII and NYHAIV severity of heart failure according to WHO classification [21]. The number of drugs consumed by those patients in both arm of study exceeded 4 drugs for different co morbidities and this poly pharmacy in elderly patients may reduce adherence to medications that need more strict care and monitoring [22]

In the present study, the self-care of heart failure index (SCHFI) was used of three major domains to assess the capability of patients with heart failure (HF) for self-care to reduce the frequency of hospitalizations that are caused by decomposition. The baseline pre discharge value of SCHFI in the current study showed lower total score (44.7±6.5vs45.8±7.9)of program and control group patients respectively, with no significant differences between groups (*P* value >0.05) and this may reflect poor awareness by patients which possibly explained by a lack of motivation to adhere to the recommendations. severity of heart failure in patients with both moderate heart failure (NYHAIII) and in severe heart failure (NYHAIV) was strongly and equally improved after 12 weeks of follow up among program patients in comparison with control group in most of SCHFI domain and acceptable improvement in confidence domain of SCHFI (*P* value ≤0.05) in patients with severe heart failure (NYHAIV). Each drop of LVEF by 5% was related with 25% worsening of self-care and vice versa Lycholip E et al. (2018) [23]. The data confirmed by Sedlar N et al. (2017) who showed a significant correlation between self-care and status of functional capacity, depression existence and left ventricular function (as a predictor of disease severity). Depression and anxiety are prevalent among HF patients and are linked to a worse quality of life, self-care, bad prognosis and inadequate educational programs efficiency [24]. On the other hand, HF patients on usual care in this study had no improvement in self-care domains irrespective of the disease severity. Finally, Nieuwenhuis et al. (2012) concluded that patients in NYHA II mostly had lower long-term compliance in comparison to those in NYHA class III or IV, probably because of lacking of motivation for recommendations adherence in case of moderate HF symptoms [25].

Adherence to medication regimens is a key behavior in acute HF with pharmacist mediated intervention through patient education and follow up has considerable impact on optimizing patient' medication adherence [26]. patient's adherence assessed by BMQ tool in this study. On average, most of patients were classified as New York Heart Association class III pre-hospitalization, in both moderate heart failure(NYHAIII) and severe heart failure (NYHAIV) patients obtained equal improvement in specific necessity, specific concerns scores and decrease in general harm, general overuse scores, after implementing study program compared to patients on usual care which lead to decrease re hospitalization. No previous data available, hence it can be speculated that poor adherence to medications is a common cause of hospital readmission among heart failure (HF) patients particularly among symptomatic HF with refractory EF (EF <40%).

For all patients living with chronic, progressive illness, maintaining a good quality of life (QOL) is as necessary as survival to them. Individuals with heart failure have poor QOL in comparison with other chronic diseases, and associated with high hospitalization and mortality rates [27]. In a study accomplished by Erceg et al. (2013), it was noticed that advanced NYHA class, poor socioeconomic status, longer standing of chronic heart failure, presence of co morbidities, lack of social and familial support and increased number of medications, are the predominant

indicating factors of poor QOL in elderly patients [28]. The effect of the pharmacist-based program on quality of life of HF patients post discharge presented with more predominant improvement among patients with moderate heart failure (NYHA III) in the 4 domains of QOL, after 12 weeks of follow up. Meanwhile patients with severe heart failure (NYHA IV) had a lower benefit from the program; there are a few published data to interpret these findings, but this could be correlated with the reducing self-care confidence mentioned earlier and disease complications despite of their good awareness and adherence to medication.

A number of biomarkers associated with HF are well recognized, and measuring their concentrations in circulation can be a convenient and noninvasive approach to provide important information about disease severity and helps in the detection, diagnosis, prognosis, and management of HF[29]. After adjustment of HF patients sub groups according to the severity of AHF, serum levels of BNP and troponin I among program patients were significantly improved (P value ≤0.01) after pharmacist intervention, although it still above the target level, this is because most of patient presented with great risk of all-cause mortality associated with ventricular dysfunction and accordingly correlated with poor quality of life. Another clinically available disease severity measure was the ejection fraction that monitor the improvement in functional capacity of the heart, acute decompensation of the heart is defined by reduced ejection fraction (<40%), which was the baseline value of the AHF patients enrolled in this study, and markedly improved at the study end line among intervention patients compared to the usual care, reflecting the endpoint of the pharmacist-based program. Several studies reported that prognosis associated with HF moderate EF (40≤EF<50%) within the first year following hospitalization is similar to HF with preserved EF (EF≥50%) and to HF with reduced EF (EF<40%) within one year after hospitalization, in addition survival was only slightly better among patients with HF-pEF than for those with HF-rEF, Choi et al.(2017), Owan et al.(2006), Fonarow et al.(2007))[30-32]

Finally, in both moderate (NYHA III) and severe (NYHA IV) heart failure patients under the program, the improvement in SBP and ejection fraction was pronounced more in patients with severe heart failure (NYHA IV) since both markers predict worsen prognosis and mortality.

Conclusion:

The obtained evidences by the mentioned studies emphasize the potential participation of pharmacist interventions to the improvement of patients self-care with heart failure, improving their clinical status, exercise capacity, and quality of life, preventing re-hospitalizations and a reduction in total mortality at the endline of study among intervention patients (program group) compared to the usual care (control group).

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