Original Article

Effectiveness of a Pharmacist-led Heart Failure Management Program in Improving Patient Outcomes

Zainab Zakaraya[1]*, Mohammad Abu Assab[2], Marwah Thamer Alsaadi[3], Dimah Azizi[4], Afaf Nowwara[5], Inas Almazari[6], Wael Abu Dayyih[7]

[1]Faculty of Pharmacy, Al-Ahliyya Amman University, Amman 19111, Jordan.
Email: z.zakaraya@ammanu.edu.jo
[2]Department of Clinical Pharmacy, Faculty of Pharmacy, Zarqa University, Zarqa 13110, Jordan.
Email: mabuassab@zu.edu.jo
[3]Pharmacy College, Al-Muthanna University-Samawah 66001, Iraq.
Email: marwa-thamer@mu.edu.iq
[4]Clinical Fellow, Paediatric Cardiology, Great Ormond Street Hospital, England.
Email: dimah.azizi@gmail.com
[5]Faculty of Nursing, Al-Zaytoonah University of Jordan, Amman 11733, Jordan.
Email: a.nowwara@zuj.edu.jo
[6]Department of Clinical Pharmacy, Faculty of Pharmacy, Zarqa University, Zarqa 13110, Jordan.
Email: ialmazari@zu.edu.jo
[7]Faculty of Pharmacy, Mutah University, Al-Karak 61710, Jordan.
Email: wabudayyih@mutah.edu.jo

Abstract

Background: Heart failure (HF) is a serious and expanding medical condition for which there are still difficulties in managing co-morbidity, non-adherence to therapy, and the coexistence of consequences. Numerous studies have attempted to decrease the rate of hospitalization among patients with HF by using an all-encompassing and multidisciplinary strategy, whereas medication compliance was rarely measured. **Aim of Study**: To evaluate the effect of pharmacist care on patient outcomes in heart failure (HF). We aimed to ascertain how a pharmacist-led intervention affected heart failure patients' adherence to their prescription regimens. **Methodology**: We investigated the effect of a pharmacist-led intervention on medication compliance in heart failure patients who were admitted to Jordanian hospitals or who showed up at an outpatient cardiology clinic while using loop diuretics (This is inclusion criteria for study). A randomized controlled trial was used for the investigation. Over six months, patients in the intervention group saw their community pharmacist once a month. The control group's patients got standard care. A digital tablet bottle that records the opening moment was used to assess the medication event monitoring system. Furthermore, data on the number of readmissions, deaths, and life expectancy were obtained. 200 patients were randomized; 102 were placed in the intervention group and 98 in the control group, receiving standard care. **Results**: During the six-month study time frame, individuals in the usual care group took loop diuretics for 335/6191 days (the relative risk was 0.31 [confidence interval (CI) 95% 0.23–0.39]), compared to 145/7651 days for patients in the intervention group. **Conclusion**: Even in case of individuals with relatively high compliance, a pharmacy-led approach can further increase medication compliance specially with those patients who are suffering with moderate to severe HF. Pharmacist care in the treatment of patients with HF greatly reduces the risk of all-cause and HF hospitalisations. Less compliant patients should also be the focus of future interventions.

Keywords: Heart Failure (HF), Adherence, Drug Monitoring, Pharmacist-led Program.

Introduction

Heart failure (HF) is a medical condition marked by recurrent symptoms, including tiredness, dyspnea, and ankle swollen. Peripheral edema, pulmonary crackling, and high jugular vein pressure are among the symptoms that can be identified. An anatomical or physiological heart abnormality causes these symptoms, which lower cardiac output and raise intra-cardiac pressures during rest or stress.[1] It is characterized by an unacceptably high risk of hospital readmission, a poor prognosis, and high rates of morbidity and death. Several comorbidities sometimes compound it. The elderly have a significant illness burden, and overall prevalence is high and rising.

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Address for Correspondence: Faculty of Pharmacy, Al-Ahliyya Amman University, Amman 19111, Jordan
Email: z.zakaraya@ammanu.edu.jo

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With an estimated 38,000,000 individuals worldwide living with HF, the burden on the healthcare system associated with it is rapidly rising.[2]

Functional ability is restricted by HF, which negatively impacts quality of life and places a significant financial strain on health care. Despite better results from medical care, new research reveals that approximately fifty percent of hospitalized patients with heart failure are readmitted within six months, and twenty-five percent are readmitted within thirty days of release.[3] Furthermore, five years after diagnosis, 50% of patients pass away. Since HF frequently coexists with polymorbidities and polypharmacy, creative interdisciplinary collaborative treatments, including pharmacists, are necessary.[4]

Numerous studies have attempted to enhance outcomes by reducing heart failure patients' rehospitalizations by using a thorough, multidisciplinary approach. Nevertheless, these studies seldom ever examined drug compliance, or when they did, the methodology was rarely reliable.[5] Using pill counts, two trials that evaluated compliance revealed improvements in the intervention group. Medication event monitoring systems (MEMS) were utilized in just 1 research to evaluate medication compliance using a more advanced technique. However, it only included a two-month follow-up period and a rather small sample size of 50 patients.[6,7]

Prior studies of patient interventions for heart failure have involved significant contributions from specialized nurses. A pharmacist has been a part of a multidisciplinary intervention in a few trials to increase compliance. Although several fewer investigations have examined the autonomous role of pharmacist's independent roles, they have not used adequate procedures to measure adherence and have used clinical or laboratory pharmacists who have received specific education for the intervention.[8-10] In this randomized managed research, we investigated the improvement of a community pharmacist-led program intervention on heart failure patients' compliance with medication. The study involved Eighty Jordanian pharmacists and three hospitals examines the most recent and reliable data addressing the pharmacist's function in the multidisciplinary team for HF therapy to enhance clinical outcomes.

Globally, cardiovascular diseases (CVDs) constitute the leading cause of mortality. 17.9 million fatalities worldwide in 2019 were related to CVDs, with 75% of these deaths occurring in low- and middle-income countries. In 2019, illnesses that are not communicable

were responsible for 17 million premature deaths (deaths lower than 70 years old), of which cardiovascular diseases (CVDs) accounted for 38%.

One of the most famous forms of CVD is HF, HF is a serious medical and financial issue. Any alterations to the structure or function of the heart that impact the ventricle's ability to fill with or empty blood might cause this progressive clinical condition.[11-13]

Pharmacist interventions were defined as pharmacist-directed care (pharmacist-initiated and directed intervention) or pharmacist collaborative care (member of a multidisciplinary team); these were delivered in a range of settings.

Numerous comprehensive reviews have been carried out to investigate the impact of pharmacist treatment on heart failure patients. One of them by Koshman *et al.*[14] included RCTs (randomized controlled trials) that estimated the impact of pharmacist therapy on heart failure outpatients as well as inpatient settings before August 2007.[14-17] In a distinct study by Sanchis-Gomar *et al.*[18], both RCTs and prospective observational studies included people with acute coronary syndrome (ACS), HF, coronary artery disease (CAD) and left ventricular dysfunction (LVD).[14] Furthermore, through March 2017, a different study by Parajuli *et al.*[6] evaluated the effectiveness of multidisciplinary HF management incorporating pharmacists in English-language RCTs conducted in various contexts.

According to numerous studies carried out in various nations, heart failure patients who take their medication as prescribed have reduced rates of heart failure exacerbations, increased survival, fewer ER visits, and lower healthcare costs. Problem statement of this study is that increased hospitalization, deteriorating symptoms, accelerated disease progression, and an overall rise in healthcare expenses and emergency room visits are all linked to non-adherence to HF treatment. HF medication adherence rates are consistently below optimum across trials, according to research done elsewhere with various medication adherence evaluation instruments. The objective of this study includes that pharmacist-led medication therapy management (MTM) service implementation is critical to achieving targeted therapeutic outcomes and lowering medication non-adherence difficulties of heart failure (HF) patients.

Heart Diseases

The term "heart failure disease" refers to a broad spectrum of heart-related illnesses. These illnesses may differ significantly in terms of their genesis, signs, severity, and impact on overall health and well-being. Infections, autoimmune diseases, genetics, allergies, environmental factors, and other underlying conditions can cause heart problems. These may impact people of various ages and socioeconomic levels.[19]

The Link between Pharmaceutics and Heart Failure

Pharmacist treatment considerably decreased the risk of hospitalizations for all causes of heart failure (HF), and it also did not significantly decrease death, according to a prior comprehensive analysis of randomized controlled trials (RCTs). Being a member of a multidisciplinary team made the pharmacist's decreased risk much more apparent. Integrating guideline-directed medical therapy (GDMT), which is endorsed by Australia, into a multidisciplinary strategy to treat HF is essential—America, as well as professional associations around Europe.

Recent research has demonstrated that the management of HF can be significantly improved by multidisciplinary teams that include pharmacists. One such team can optimize GDMT for patients with declining ejection fraction in HF. Decrease in 30-day readmissions for all causes, shorter time to first follow-up, a secure transfer of

patients from inpatient to outpatient treatment, as well as general drug administration. Notwithstanding this data, there are still questions about the specific function of the pharmacist in an interdisciplinary group. To enhance clinical outcomes, this study investigates the most recent and reliable data regarding the pharmacist's function in the multidisciplinary team for HF therapy.[20]

Methods

Study Population

Inclusion Criteria

The study could only include participants receiving loop diuretic treatment. Heart failure patients either visited a specialized outpatient clinic for heart failure or were hospitalized at one of the collaborating hospitals. The patient's medical records and the results of cardiac imaging were used to validate the HF diagnosis.

Exclusion Criteria

Individuals whose anticipated lifespan was fewer than three months, serious psychiatric disorders or dementia, planned nursing home admission, and medication non-adherence (i.e., filled or administered by family members or district nurses) were not eligible for this study. Study was conducted and patients were enrolled between July 2022 and February 2024.

Program for Intervention and Customary Care Group

Cardiologists briefed patients about the trial. Following the receipt of signed consent, participants were randomized to either the usual care arm or the intervention arm using a computer-generated randomization process. The patient's general practitioner (GP) and pharmacist were informed about their participation in the trial. A group of pharmacists was trained in the intervention, which consisted of a structured interview conducted during the patient's initial visit to the neighborhood drugstore following enrollment in the experiment. A computerized medication history was used to address drug usage, noncompliance reasons (including possible adverse drug reactions and difficulties incorporating medication use into daily life), and medication use to increase medication compliance. The general practitioner was issued a brief report on this interview. Following that, patients were contacted by pharmacists once a month for a maximum of six months. Neither the structured interview nor the monthly follow-up was provided to patients in the usual care group.

Measurement of Compliance

Every patient who consented to participate in the research was given their loop diuretics in a MEMS, a medication container with a microchip that tracked the opening time and date. The patient's usual pharmacist filled the MEMS container. Pharmacists collected containers after follow-up and submitted them for computer-based reading and assessment. The real dosing schedule for patients was obtained from hospital records. The patients completed a questionnaire about their use of the MEMS. Patients were permitted to "shift" their dose schedule from dawn until dusk. Days without a dose during the planned dosage were evaluated. Patients who were given temporary advice to take the diuretic on and off were not regarded as non-compliant.

Data Collection

Pre-tested structured questionnaires and data abstraction tools were used, respectively, to gather clinical and demographic information from research participants. The data collection was done by clinical pharmacists who had received training. At the same time, clinical pharmacists reviewed clinical data and provided patient education. The Morisky Green Levin Medication Adherence Scale (MGL) was used to determine medication adherence. There are four items with closed dichotomies (yes/no) that center on historical medication use patterns. Every "no" response received a score of 1, while every "yes" response received a score of 0. The overall summed score, which goes from 0 to 4, is divided into three categories: poor adherence (≥3 points), medium adherence (1-2 points), and high adherence (0 points).

Measures of Outcome

The primary outcome assessed between the pre-intervention (baseline) and post-intervention periods was the shift in medication adherence rate. MGLS assessed the shift in the medication adherence rate.

Statistical Analysis

Before exporting the data to the statistical program GraphPad Prism, the data were sorted, cleaned, coded, and entered Epidata. Descriptive statistics were used to summarize the frequencies, means, and percentages. To investigate the association between the predictor variables and medication adherence, the study used binary logistic regression modeling. A multivariable binary logistic regression analysis was performed, considering all characteristics with $p<0.25$ in the univariable binary logistic regression study, to find potential predictors of medication adherence. P-values were considered statistically significant if they were less than 05.

Results

Participants' Initial Characteristics

In all, eighty pharmacies took part in the research. Out of the 200 patients that were part of the study, 98 were assigned to the pharmacy-led intervention and 102 to the conventional care group at random. Most of the patients were Jordanian men. The two groups' comorbidities and medication histories were similar. The kind, daily dosage, and dosing schedule of loop diuretics were all the same (Table 1). Figure1 demonstrates the Participants' initial characteristics. Figure 2 demonstrates the medical history of the participants. Figure 3 demonstrates creatinine (µmol/L), sodium (Na) (mmol/L), potassium (K) (mmol/L) and hemoglobin (Hb) (mmol/L). Figure 4 demonstrates Blood Pressure. Figure 5 demonstrated body Mass Index. Figure 6 demonstrated prescription drugs for cardiovascular conditions in addition. Figure 7 demonstrates the first schedule of dosages. Figure

8 demonstrates the type of diuretic.

Angiotensin-converting enzyme is ACE, and the recommended daily dosage is PDD. Since furosemide 40 mg or bumetanide 1 mg = 1, * the values are expressed Mean ± SD, where Age, The years after HF diagnosis, Na (sodium), K (potassium), Hb (hemoglobin), BMI (body mass index), The blood pressure's systolic (mm Hg), and Blood pressure at diastolic levels (mm Hg).

Table 1: Participants' Initial Characteristics.

	Pharmacy-Led Intervention (n=102)	Usual Care (n=98)
Age (Mean, SD)	60.1 ± 10	69.1 ± 11
Male (n, %)	72(70)	58 (59)
The years after HF diagnosis (Mean, SD)	1.9± 1.5	1.9± 1.6
Comorbidity visiting HF clinic (n, %)	72 (70)	62 (63)
Myocardial infarction	58 (56)	49 (50)
Hypertension	35 (34)	44 (43)
Arrhythmias	49 (48)	57 (58)
Renal insufficiency	14 (13)	10 (10.2)
Diabetes	27 (26)	30 (30.2)
Obstructive pulmonary disease	18 (18)	20 (20.2)
Laboratory (Mean, SD)		
Creatinine (µmol/L)	120 ± 38	130 ± 60
Na (mmol/L)	141±2	141± 3
K (mmol/L)	5.2±0.5	5.2± 0.5
Hb (mmol/L)	9.2±0.8	9.2± 1.2
BMI	27±5	27± 4
The blood pressure's systolic (mm Hg)	123±21	123±22
Blood pressure at diastolic levels (mm Hg)	74±12	77±12
Prescription Drugs for Cardiovascular Conditions, in Addition (n, %)		
1. ACE inhibitor	69 (67)	60 (61)
2. Acetylsalicylic acid or anticoagulant	91 (89)	81 (83)
3. All antagonist	20 (20)	15 (16)
4. Antiarrhythmic	15 (14.7)	8 (7.8)
5. β-blocker	30 (29)	31 (31.6)
6. Calcium entry blocker	9 (8.8)	8 (8.1)
7. Cholesterol-lowering agent	25 (24.5)	18 (18.3)
8. Digoxin	50 (49)	41 (41.8)
9. Organic nitrate	41 (40)	39 (40)
10. Spironolactone	30 (29.4)	28 (28.5)
Type of Diuretic		
1. Furosemide	74 (73)	52 (53)
2. Bumetanide	30 (29.4)	29 (29.5)
3. Average PDD*	2.8	3.2
The First Schedule of Dosages		
1. Once daily	59 (58.1)	54 (56.1)
2. Twice daily	34 (42)	39 (39.7)
3. >twice daily	9 (8.8)	5 (5.1)

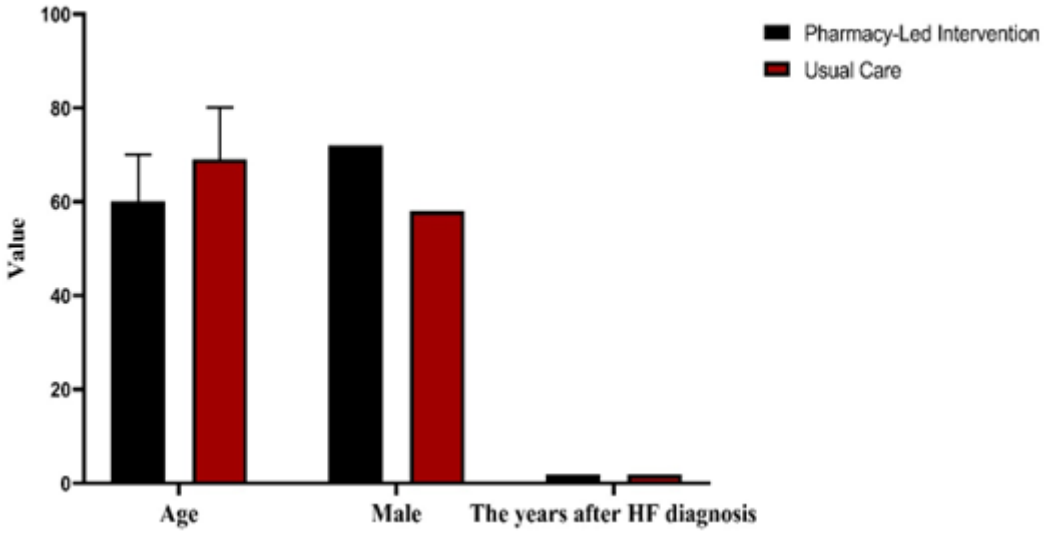

Figure 1: Participants' Initial Characteristics.

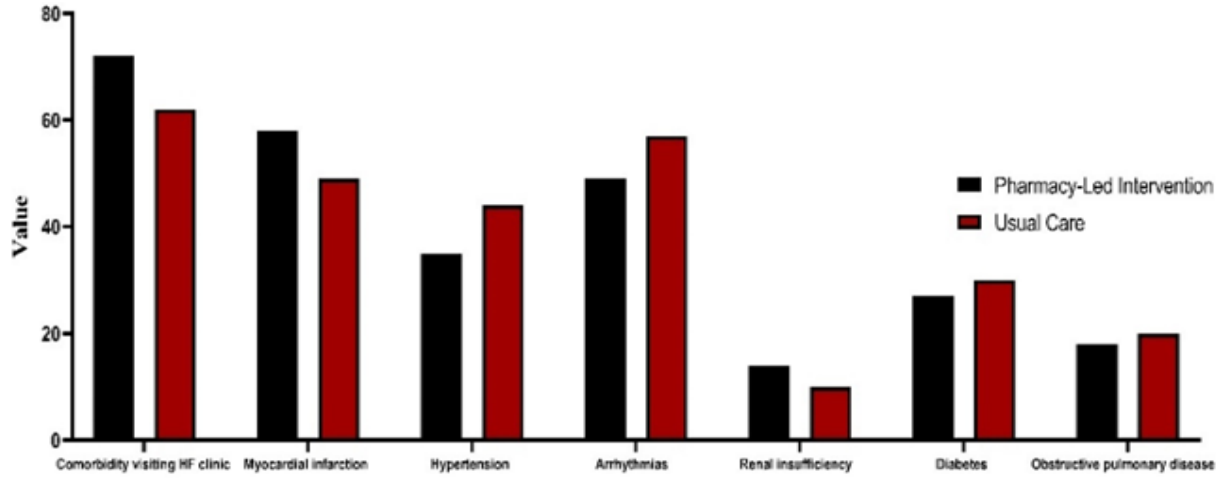

Figure 2: Medical History of Participants.

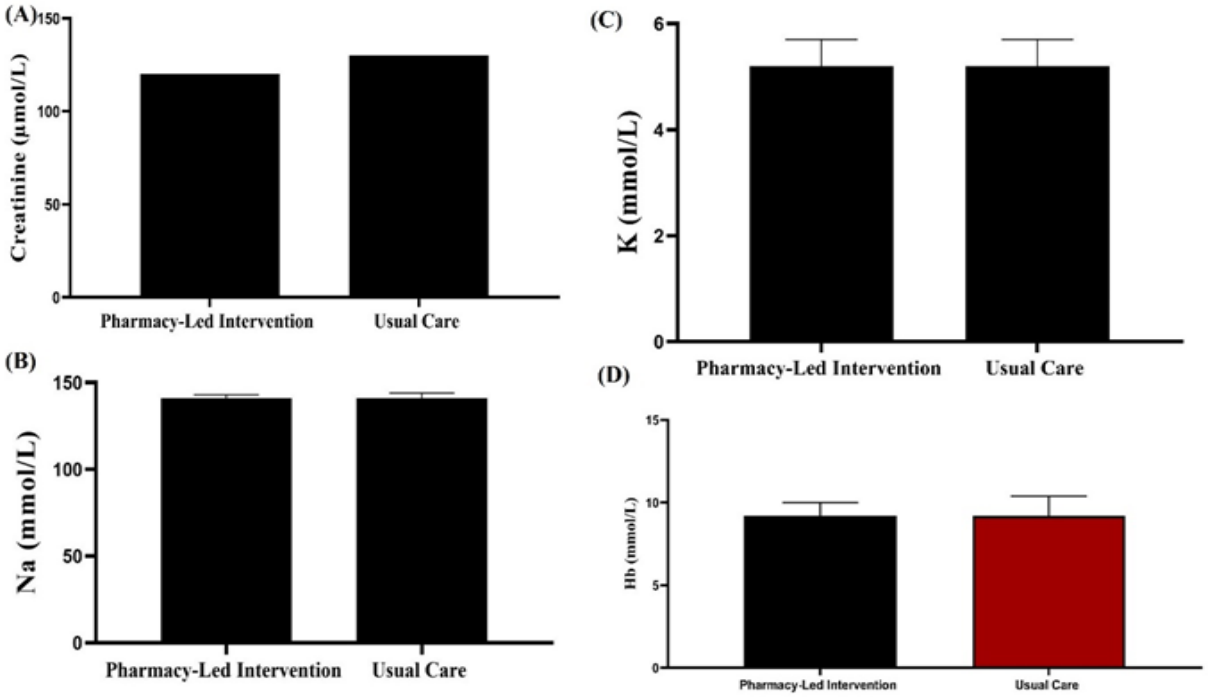

Figure 3: Creatinine (µmol/L), Sodium (Na) (mmol/L), Potassium (K) (mmol/L) and Hemoglobin (Hb) (mmol/L).

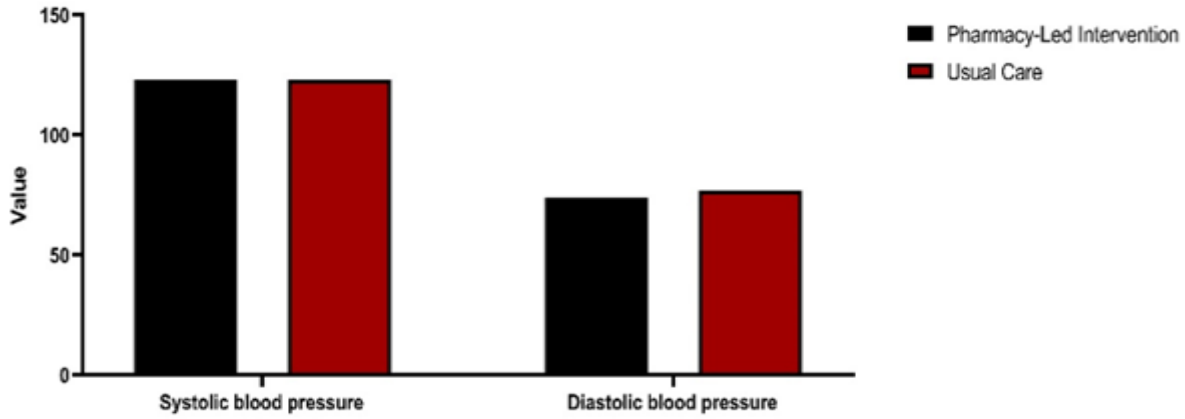

Figure 4: Blood Pressure.

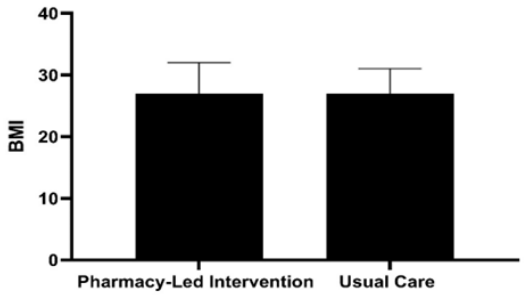

Figure 5: Body Mass Index.

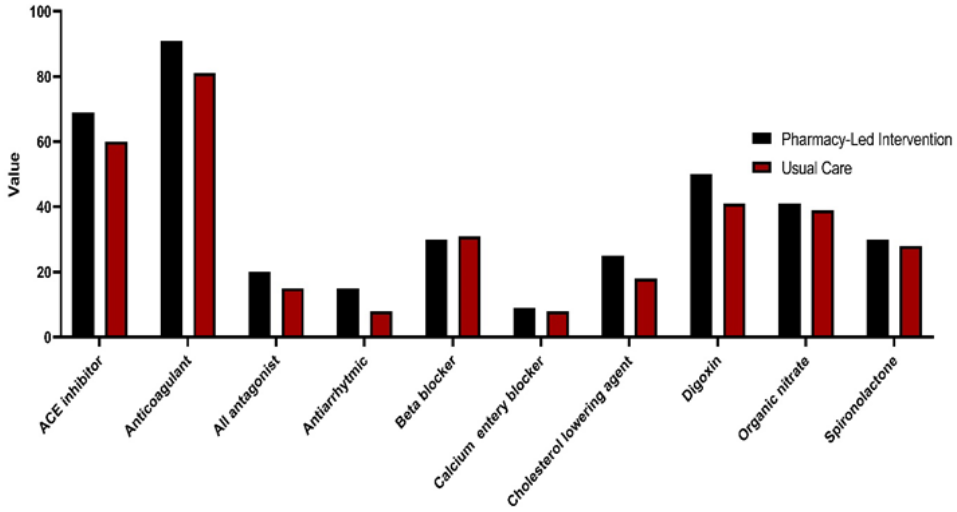

Figure 6: Prescription Drugs for Cardiovascular Conditions.

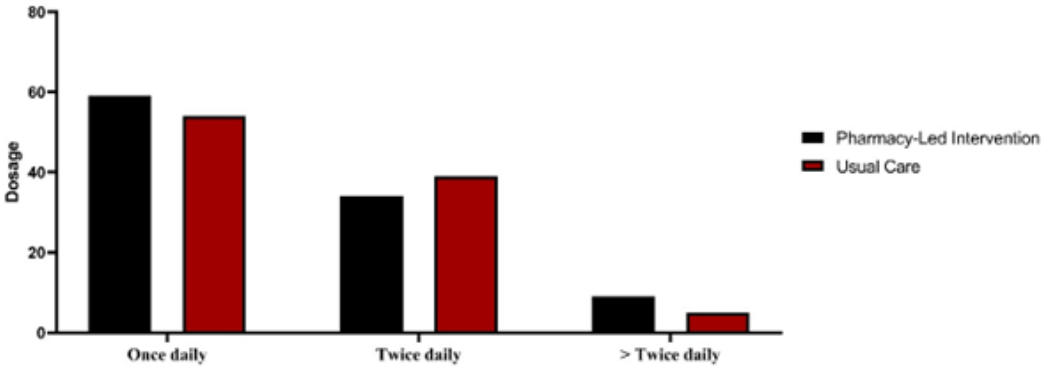

Figure 7: The First Schedule of Dosages.

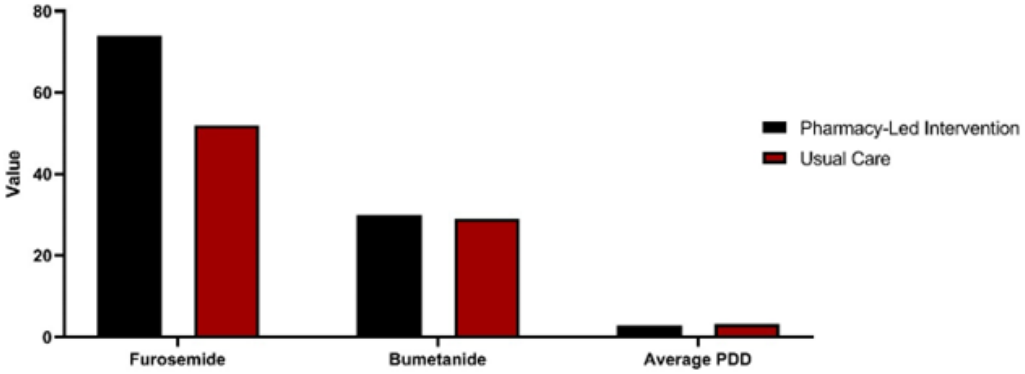

Figure 8: Type of Diuretic.

Patients' Adherence to MEMS Data

MEMS use lasted an average of 145.6 days in the routine care group and 165.3 days in the intervention group. Individuals within the pharmacological group did not use loop diuretics for 145/7651 days (proportional risk 0.31 [Interval of confidence (CI) 95% 0.23–0.39]), as opposed to 335/6191 days in the customary care unit. Compared to 48/6191 days in the usual care group, there were 20/7651 days in the interventionist organization where diuretics were not used (proportional risk = 0.31 [CI 95% 0. 21–0. 61]). (Refer to Table 2) Figure 9. demonstrates patients' adherence to MEMS data

Table 2: Patients' Adherence to MEMS Data.

	Interventionist Organization (n=45)	Customary Care Unit (n=40)	Proportional Risk (n=40)
Average age (years)	67.9	67.3	
Men	33 (73)	31 (77)	
Average number of days without a dose	2.8	7.6	
Period of usage MEMS	157.5	142.1	
Days spent in total on MEMS	7651	6191	
Days without taking medication	145/7651	335/6191	0.31 (0.21–0.41)
≥2 consecutive days without dosing	20/7651	48/6191	0.31 (0.21–0.61)
Less than 80% compliance	0 (0)	8 (20)	0.52 (0.41–0.62)
Less than 95% compliance	9 (20)	15 (37.5)	0.31 (0.12–0.91)

Medication event monitoring system, or MEMS. Each value is expressed as a percentage.

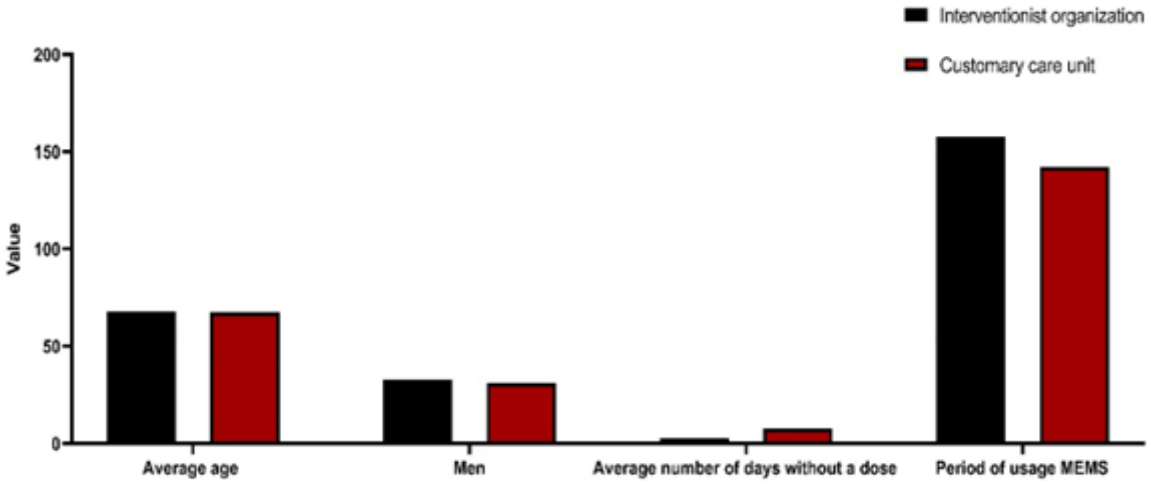

Figure 9: Patients' Adherence to MEMS Data.

The Standard of Living among Patients who have Access to Questionnaires

Both the intervention group and the usual therapy group saw improvements in their quality of life related to the condition. There was an advantage to more improvement in the normal care group. Nonetheless, there was no significant statistical change. The overall standard of living measures (COOP/WONCA) somewhat decreased in the intervention group while improving in the group getting routine care. The Kaplan-Meier time to adherence was examined for 365 days following heart failure and is shown in Figure 10.

Table 3: The Standard of Living among Patients who have Access to Questionnaires.

	Pharmacy-Led Intervention			Usual Care			*P*
	Initial (n=50)	Six Months (n=45)	Change* (n=45)	Initial (n=53)	Six Months (n=35)	Change* (n=35)	Value
COOP/WONCA	21.6±4.7	19.4±5.6	0.4±3.8	23.1±5.11	19.8±5.3	-2.6±6.2	0.04
MHFQ	41.1±21.3	32.8±21.3	-2.4±14.2	48.0±22.4	36.9±21.3	-12±22.9	0.08
Realm of the physical	19.7±8.2	16.7±9.7	-0.7±5.8	23.4±9.8	17.9±9.7	-4.7±10.6	0.08
Domain of emotions	8.4±6.2	6.7±6.4	-1.3±3.7	9.6±7.3	8.2±6.4	-1.7± 6	0.7

* Lower scores on the questionnaires indicate better quality of life; mean and standard deviation of scores are provided.

* COOP/WONCA, Dartmouth Primary Care Cooperative Information Project/World Organization of National Colleges, Academies, and Academic Associations of General Practice/Family Physicians; MHFQ, Minnesota Heart Failure Questionnaire Only patients whose baseline and 6-month questionnaires were available were included in the calculation of change.

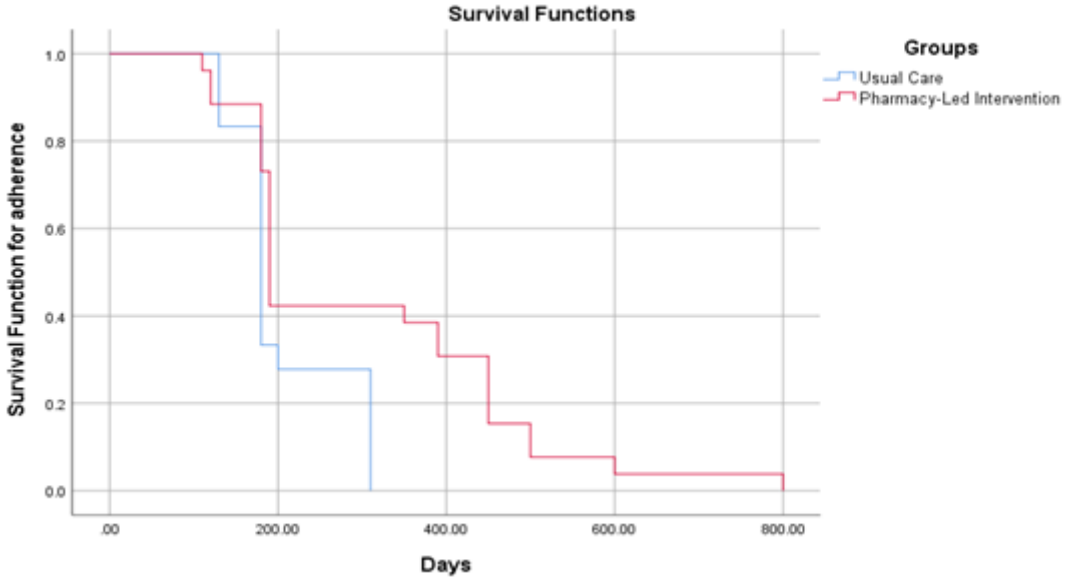

Figure 10: Kaplan-meier Survival Estimates for Adherence.

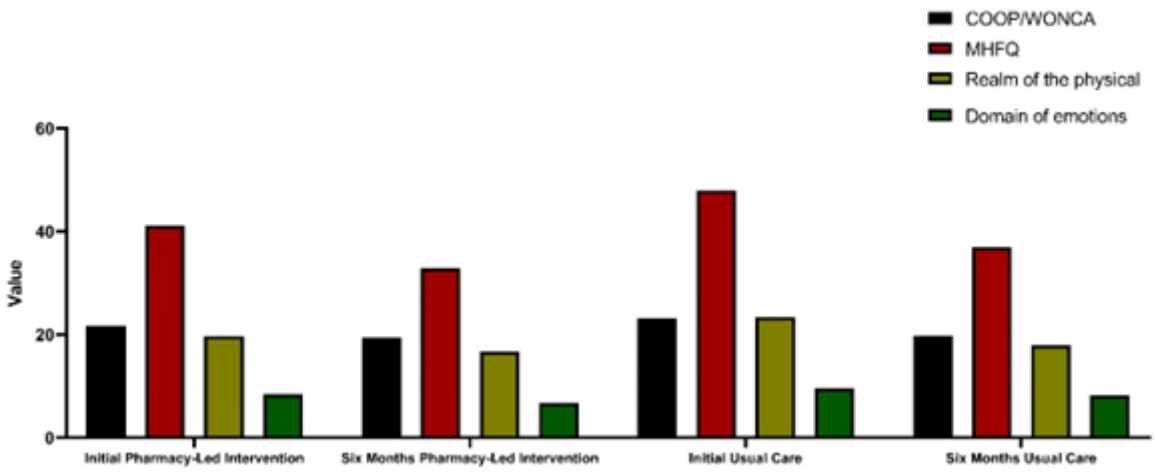

Figure 11: The Standard of Living among Patients who have Access to Questionnaires.

Discussion

Heart failure (HF) affects one to two percent of the adult population in developed nations and is a common, extremely morbid, chronic, progressive, and expensive disorder with an increasing influence on public health. Drug treatment for heart failure patients that follow guidelines is getting more complicated.[20,21] It can improve quality of life (QoL) and physical performance and lower hospitalization and mortality rates associated with heart failure (HF).[1]

Medication, however, is given to patients in large doses; these may include diuretics, beta-blockers, aldosterone antagonists, neprilysin inhibitors, sodium-glucose cotransporter-2 inhibitors, ivabradine, digoxin/digitoxin, vericiguat, hydralazine/nitrates, and other drugs.[22]

The syndrome's difficulty, multiple medical conditions, and heterogeneity raise the risk of serious side effects, patient perplexity, and therapy non-adherence. Medication non-adherence is the most significant factor contributing to heart failure exacerbations, along with drug interactions, contraindications, redundant prescriptions, unpleasant side effects, and unpleasant effects. Improving medication adherence has been linked to fewer hospital admissions and a lower death rate.[23]

The present investigation demonstrated that patients with moderately to severe heart failure can increase their diuretic concordance with a pharmacist-led intervention. Allocation to the intervention group was the only factor that continued to be substantially linked with increased compliance after multivariate analysis. In both the intervention and usual care groups, compliance was found to be surprisingly high (meaning ~91%). According to additional research, about half of senior heart failure patients do not completely.[24] Seventy-eight percent of the patients also went to a specialty heart failure clinic to increase adherence to diet and medication. The impact of these visits is demonstrated by the comparatively large proportion of patients who were prescribed spironolactone, β-blockers, and inhibitors of the angiotensin-converting enzyme (ACE) at baseline.

Before being admitted to our trial, all eligible patients were given preliminary written and spoken information to help them give their informed permission. Likely, patients who weren't willing to engage did so on purpose. It has been demonstrated that consenting patients differ from nonconsenting patients.[25] In randomized clinical trials testing novel medications, selecting individuals who have a favorable attitude about healthcare may be helpful, but it may dilute the efficacy of more practical "care interventions." Since patients were randomized rather than pharmacies, pharmacists may have patients in both the standard care and intervention groups. Relative contamination will only have lessened the intervention's impact, even if we believe that cross contamination will be minimized, given only 28% of participating pharmacists were dispensing for both the intervention and usual care groups. Insurance covers prescription medication reimbursement for all patients in the Netherlands. Therefore, socioeconomic variations are less of a problem for compliance, unlike in some other countries. Lastly, it's possible to view the actual usage of MEMS in the usual care group as an intervention that also helped to increase compliance.[26] Our results are consistent with data from Rich et al., who used pill counts to determine medication compliance and discovered that intervention patients had an average compliance of 87.9% as opposed to 81.1% in the usual care group.[27]

The quality of life improved for both the intervention and standard treatment groups, most likely because of the disease's natural course. Patients who were included in the trial as soon as they were admitted to the hospital showed a notable increase in their quality of life. Quality of life, as indicated by the COOP/WONCA charts that are not disease-specific, improved more in the group receiving standard care. Fewer patients in the usual care group who had a lower quality of life at six months completed the quality-of-life questionnaire, which may account for the higher improvement in that group. During their regular interactions with the pharmacist, patients in the pharmacy-led intervention were urged to fill out this questionnaire. We must conclude that this intervention did not enhance the patient's quality of life when compared to other interventions they got (78% of whom went to a specialty clinic for heart failure).

In other research, a small group of specialized nurses worked in conjunction with other hospital-based clinicians to handle the patients. Despite being enrolled in the hospital, the patients in this trial received assistance from their usual community pharmacists. It is simpler to use the results in everyday practice because of this practical approach. There were certain logistical issues with this design, especially when patients who were most at risk of mortality or serious morbidity returned to their MEMS monitors. We were thus denied access to dosage history data that would have contained vital information

Conclusion

This study demonstrated that community pharmacists can enhance heart failure patients' medication compliance, even in individuals who already had relatively good compliance. Future interventions should target patients who are more likely to not comply with treatment, with a particular emphasis on enhancing adherence in those using medications that change the course of heart failure naturally, including ACE inhibitors and β-blockers. It makes sense to include community pharmacists in multidisciplinary treatments since patients must always visit their pharmacy to pick up their medicine. Prerequisites would include patients sticking to one neighborhood drugstore and neighborhood pharmacists working with other medical professionals, as in this trial. It will be challenging to implement a fundamental role for the neighborhood pharmacist in nations where mail-in prescriptions without direct interactions with pharmacists are usual.

Recommendation

HF readmission rates can be decreased even in a sophisticated multiracial/ethnic diverse community with robust Medicaid coverage. Patient results can be enhanced by a team approach to therapy and the involvement of PharmDs with HF training who collaborate with an HF cardiologist. Even though it's unclear if the approach here will apply to all care settings, further research is still beneficial.

Declarations

Ethics Approval and Consent to Participate

Not applicable.

Consent for Publication

Not applicable.

Declaration of Generative AI and AI-assisted Technologies in the Writing Process

During the preparation of this work, the author(s) did not use generative AI and AI-assisted technologies in the writing process.

Availability of Data and Materials

All data generated or analyzed during this study are included in this published article. Also, the materials and any of the plants used in the current study are available from the corresponding author upon reasonable request.

Competing Interests

The authors declare that they have no competing interests.

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