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IMPACT OF PHARMACEUTICAL CARE IN POST DISCHARGE MANAGEMENT OF PATIENTS WITH HEART FAILURE

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ABSTRACT

The aim of the randomized prospective study was to assess the importance of pharmaceutical care in heart failure patients for improving their medication adherence and quality of life. since; this syndrome is associated with high rates of mortality and morbidity, including hospital readmission thereby posing a significant societal burden. The results showed that patient compliance during follow up was found to be 96.24% and for Intervention group it was reported as 95.95%. Readmission rate for intervention was found to be 40% in 22 patients and that of control was 47.65% in 23 patients. By participating in this study the quality of life of the patients in the Intervention Group was stabilized in several subscales indicating that the quality of life can be altered by patient counselling. Also, it was observed that pharmacist intervention had only a limited effect on health related quality life outcomes in Chronic heart Failure (CHF).

KEYWORDS: Heart failure, Medication adherence, Patient compliance, Quality life, Intervention.

INTRODUCTION

Heart failure is one of the largest medical problems of our time, despite substantial advances in its treatment, morbidity and mortality remains high in recent years.[1] The incidence of heart failure is increasing in developed and developing countries. In the aged population, heart failure is a common cause of hospitalization and hospital readmission which in conjunction with post-discharge care, impose a significant cost burden.[2] Inappropriate

medication management and drug-related problems have been identified as major contributors to hospital readmissions. In order to enhance the care and clinical outcomes, and reduce treatment costs, heart failure disease management programmes (DMPs) have been developed.[3] It is recommended that these programmes adopt a multi-disciplinary approach, and pharmacists, with their understanding and knowledge of medication management can play a vital role in the post-discharge care of heart failure patients. The effectiveness of multidisciplinary non-pharmacological approaches for improving outcomes in patients with Chronic heart Failure (CHF) have been well established.[4]

Common causes of heart failure include myocardial infarction and other forms of ischemic heart disease, hypertension, vulvar heart disease and cardiomyopathy.[5] Heart failure can cause a large variety of symptoms such as shortness of breath, coughing, ankle swelling and exercise intolerance. Congestive heart failure is the pathophysiologic state in which the heart is unable to pump blood at a rate commensurate with the requirements of metabolizing tissues, or can do so only from an elevated filling pressure.[6]

Heart failure is a common, costly, disabling and deadly condition. In developing countries, around 2% of adults suffer from heart failure, but in those over the age of 65, this increases to 6–10%.[7] Due to costs of hospitalization, it is associated with high health expenditure. Heart failure is associated with significantly reduced physical and mental health, resulting in a markedly decreased quality of life.[7,8] With the exception of heart failure caused by reversible conditions, the condition usually worsens with time.[9] Although some patients survive many years, progressive disease is associated with an overall annual mortality rate of 10%.

Intervention mainly involves pharmacist directed care to improve the treatment outcome of heart failure. Heart failure (HF) has an extremely high rate of readmission after index hospitalization, with up to 44% of patients rehospitalized within six months of discharge.[10,11] Recent studies have suggested that multidisciplinary disease management programs can substantially reduce the risk of readmission, with as much as a 56% reduction in HF readmissions and a 44% reduction for all-cause readmissions.[12]

An important goal is the development of a holistic approach to HF management, including both pharmacological and non-pharmacological interventions that can improve the quality of life and control symptoms in these patients.[13] The primary means of improving disease management in patients with HF are via optimization of pharmacological therapy and

improving patients' willingness to comply with the prescribed treatments and lifestyle advice, all of which require significant cooperation with and participation of patients.[14] From a pharmacological perspective, the optimal use of ACE inhibitors, diuretics, β -blockers and vasodilators improve the heart failure patient's health-related quality of life and, in the case of ACE inhibitors, extend life. Pharmacist should ensure that therapy is optimized, teach patients self-care and describe the possibilities that exist in everyday life.[15] Education/counselling should focus on the benefits to be gained from adherence to prescribed medications and on helping the patient to develop a healthy diet (in particular restricted fluid and salt intake), to stop smoking (if applicable) and to become involved in an exercise programme.[16]

Pharmaceutical care has been defined as "the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life.[17] There is an imperative for hospital-based clinical pharmacists to become involved in the management of patients with chronic illness though the process of pharmaceutical care provision. Pharmaceutical care mainly involves collaboration between healthcare professionals, working together with the patient in designing, implementing and monitoring a therapeutic plan together with patient education on their medications and disease state.[18]

MATERIALS AND METHODS

Design of study[19]

This was a Randomized prospective control study. In this study, whole study population was divided in to two group.

1. **Intervention group**

Provided a standard pharmacy care to improve the medication adherence and quality of life.

2. **Control group**

Not providing any pharmacy intervention other than current system.

Standard pharmaceutical care

Patient who randomized to the intervention group were educated (in a structured fashion) on their prescribed medication and the management of HF symptoms by the research pharmacist. Gave detailed information on HF, its symptoms, the aims of treatment, the types of medication used and their possible side-effects, diet and lifestyle changes, advice to stick

to one brand of digoxin (it having a narrow therapeutic index) and information on the action to take if doses of medication were missed. Intervention group patients were also instructed on a self-monitoring programme.

Parameters to be assessed[20]

The study assessed the outcome by using the following parameters

- Evaluating the patient / caregiver knowledge towards the HF
- Socio-economic status
- Disease status
- Patient compliance
- Quality of life

Baseline visit

During baseline visit, study provided a standard pharmacy care to improve the medication adherence and quality of life to the intervention group.

In Control group, not providing any pharmacy intervention other than current system. They will get a pharmacy service according to the current Indian system.

Follow up (After 3 months)

During follow up we assessed following parameters

- Patient compliance
- Reassessing the knowledge
- Quality of life
- Whether the patient readmitted or not

Settings and sample size

45 patients were enrolled from Department of cardiology, Medical college, Calicut, a tertiary care multispecialty teaching hospital.

Data collection

A standard data collection form was made and approved by the Ethical committee (Appendix). Demographic and other data were collected in the first interview with the patient. Patients are classified according to socioeconomic status. For this Kuppuswamy scale was used.

Demographic and clinical data were obtained from the patients medical records (medical history, demographics) and from results of clinical evaluation on the day of enrollment (heart failure signs and symptoms, laboratory values, drug therapy).

1. Interview method
2. Quality of life of the patients included in the study was assessed by using Minnesota living with heart failure questionnaire(MLWHFQ)

Inclusion criteria

- ♣ Patients in the age group of 18 years and above.
- ♣ Post discharged patient with diagnosis of HF (by a hospital consultant).

Exclusion Criteria

- ♣ Suffering any type of dementia or disabling psychiatric disease
- ♣ Refusing to participate in the study.
- ♣ Patient whose life expectancy is less than 4 months.

Method of Analysis.[21]

1. The data obtained were verified at the end of study. A statistical analysis was performed to determine the probability of significance and P value by using the Paired Sample T-test method. For the statistical analysis we use computer software SPSS 10.0.
2. Determination of Socio Economic status using Kuppuswamy scale.
3. Determination of Quality of life based on different domains.

Quality of the life in patients were measured by using Minnesotta living with heart failure questionnaire (Appendix)

Questionnaire consist of 21different questions. Outcome was measured by dividing the questions in to3 domains.

1. Overall score
2. Physical domain
3. Emotional domain

Assessment of Quality of life in intervention and control group.

Scoring is based on the severity of the symptoms shown by the patient. Score increases with increasing the severity of the symptoms. High score indicate the worsening of disease condition.

RESULTS

A total of 45 heart failure patients were enrolled in the study. Among which, 73.3% were males and 26.7% were females. The mean age of the study group was found to be 59.59±9.87 years (mean±S.D 64% had a history of 7-10 years of cardiovascular diseases. The average duration of hospitalization was 9.42±7.19 days due to either cardiovascular complications or co-morbidities prolonging the length of stay. Majority patients (67%) were managed with digoxin and loop diuretics. The mean Post Prandial Blood Sugar (PPBS)which was done on admission was found to be 263.22mg/dl (S.D=109.65) and the mean Fasting Blood Sugar (FBS) which was done during discharge was found to be 126.6 mg/dl (S.D=50.64). The study population was categorized into two groups. Details are given in the table 1.

Table 1: Details of the study.

Group	Frequency	Percentage
Control group	23	51.1
Intervention group	22	48.9
Total	45	100.0

Evaluation of Socio economic status among study group

Socio-economic status of the patients enrolled was evaluated by using modified kuppuswamy scale and was found to be 2.2% of the total study population comes under upper middle class, 24.4% comes under lower middle class, 71.1% comes under upper lower class and 2.2% coming under lower class (table 2).

Table 2: Socio Economic Status (Kuppuswamy Scale).

	Frequency	Percent	Valid Percent	Cumulative Percent
Upper middle	1	2.2	2.2	2.2
Lower middle	11	24.4	24.4	26.7
Upper lower	32	71.1	71.1	97.8
Lower	1	2.2	2.2	100.0
Total	45	100.0	100.0	

Evaluation of Disease status in control group

34.78% patients were Diabetic, 73.91% were hypertensive, 17.39% were COPD, 60.86% were CAD and 13% of patients were arrhythmic and 17% were renal failure patients.(table 3).

Table 3: Evaluation of Disease status in control group.

Disease	Control
Diabetes	45.45%
Hypertension	81.81%
COPD	27.27%
CAD	81.81%
Arrhythmia	13.63%
Renal failure	9.09%

In intervention group

45.45% patients Diabetic, 81.81% were hypertensive, 27.29% COPD, 81.81% were CAD and 13% of patients were arrhythmic and 9% were renal failure as shown in table 4.

Table 4: Comparison of co morbid condition in intervention and control group.

Disease	Intervention	Control
Diabetes	34.78%	45.45%
Hypertension	73.91%	81.81%
COPD	17.39%	27.27%
CAD	60.86%	81.81%
Arrhythmia	13.04%	13.63%
Renal failure	17.39%	9.09%

Assessment of ejection fraction

Ejection Fraction (EF1) during Baseline Investigation

Ejection fraction during base line investigation was found to be 40.05±8.89% in the case of intervention group and 41.86±6.42% in the case of control group. (table5).

Table 5: Ejection fractions of control and intervention group during baseline visit (EF1).

EF1	Group	Mean	Std. Deviation	Std. Error Mean	P value
	Intervention group	40.05	8.89%	1.99%	0.295

Ejection Fraction (EF2) during follow up

During follow up the ejection fraction of patients incuded in intervention group 44.39±5.32% and for control it was found to be 43.61±5.76%. With a significant of P= 0.890. (table 6).

Table 6: Ejection fraction during followup (EF2).

	Group	Mean	Std. Deviation	Std. Error Mean	P value
EF2	Intervention group	44.39	5.32%	1.25%	0.890
	Control group	43.61	5.76%	1.36%	

Comparison of Ejection fraction before and after Pharmacist intervention

During base line visit ejection fraction for intervention was found to be 40.05% and that of control group was 41.86%. After intervention ejection fraction of intervention group was improved with an average value of 44.05% and that of control it was 43.16%. From this result it is clear that patient coming under intervention group show better result compared to control group, with a P value of 0.061(table 7).

Table 7: Comparison of ejection fraction before and after intervention.

Group	EF1(%)(mean)	EF2(%)(mean)
Intervention	40.05	44.5
Control	41.86	43.61

Patient Compliance

Major risk factor for the worsening of the heart failure symptoms is the non-compliance towards the medication during post discharge management. This study compared patient's self-report and manual pill counts as measures of compliance, in which they were asked to assess what percentage of their medication, they did not take in the preceding study period. Here patients showing an average of 96% compliance towards the medication (minimum of 90% and a maximum of 100% compliance)with a standard deviation of 2.28%, during base line visit. (table 8).

Table 8: Compliance shown by patients during base line visit.

	N	Minimum	Maximum	Mean	Std. Deviation
Compliance	45	90%	100%	96.10%	2.28%

Compliance of intervention and control group During follow up

During follow-up as shown in table:9-

Compliance shown by control group.....95.95±2.46%.

Compliance shown by Intervention group.....96.24±2.14%.

After pharmacist intervention, intervention group shows slightly better compliance compared to control group with a significants of P= 0.558

Table 9: Compliance of intervention and control during followup.

	Group	No.of patients	Average compliance	Standard deviation	P value
Compliance	intervention	22	96.24%	2.14%	0.558
	Control	23	95.95%	2.46	

Determination of Quality of life based on different domains

Quality of the life in patients were measured by using Minnesotta living with heart failure questionnaire, details are given in table no:10.

Table 10: Minnesota living with heart failure questionnaire score during base line visit: (MLWHFQ1).

Scoring domain	Group	No.of patient	Mean of the score	Standard deviation	P value
Overall score	Intervention	22	60.33	6.78	0.553
	Control	23	60.50	4.26	
Physical domain	Intervention	22	26.90	2.57	0.649
	Control	23	26.23	2.45	
Emotional Domain	Intervention	22	12.10	1.45	0.307
	Control	23	12.55	1.82	

Intervention group shows an overall score of 60.33 with a standard deviation of 6.78 with a physical and emotional domain of 26.90±2.57 and 12.10±1.45 respectively. In the case of control group overall score was 60.50 with standard deviation of ± 4.26. physical domain was found to be 26.23±2.45 and emotional domain was 12.85±1.82 as in table 11.

Table 11: Minnesota living with heart failure questionnaire score duringfollowup: (MLWHFQ2).

Scoring domain	Group	No.of patient	Mean of the score	Standard deviation	P value
Overall score	Intervention	22	40.10	9.36	0.023
	Control	23	44.40	8.61	
Physical domain	Intervention	22	16.37	2.45	0.049
	Control	23	17.33	2.56	
Emotional Domain	Intervention	22	6.48	1.17	0.069
	control	23	7.00	1.17	

During follow up Quality of life of the intervention group shows better result compared to control, scores during follow up was found to be

Overall score---------For intervention 40.10±9.36, for control 44.40±8.61 with a Significants of, P= 0.023

Physical domain--------for intervention16.37±2.45, for control 17.33±2.56
With a significants of, P= 0.049

Emotional domain.....for intervention 6.48±1.17, for control 7.00±1.26
With a significants of, P= 0.069

DISCUSSION

The study was aimed to assess the importance of pharmaceutical care in HF patient for improving their medication adherence, and quality of life. These objectives were attained by determining the impact of post-discharge, home-based, case management intervention on the number of emergency readmissions. For the assessment, the enrolled study population was randomized in to control and intervention group. Among which, 73.3% were males and 26.7% were females. The mean age of the study group was found to be 59.59±9.87 years (mean±S.D 64% had a history of 7-10 years of cardiovascular diseases.

Socio economic status of the patients in the study group was assessed by using modified Kuppuswamy scale. There was no upper class individual in enrolled group. 1 patient belongs to upper middle class (2.2%). 11 patients in lower middle category(24.4%). 32patients were in upper lower class(71.1%). Socio economic status of the patients included in the study revealed that maximum patients included in the study were came from low socioeconomic status. Study also shown increased hospitalisation and readmission rate was more in patients came from low socio economic status compared to upper classes.

From the literature available till date, it had been found that, ejection fraction was one of the main diagnostic tool to determined the outcome measurement in the management of heart failure. During base line visit, mean ejection fraction of the intervention group found to be 40.05±8.89% and in the case of control group, 41.86±6.42%. During follow up, after pharmacist intervention, mean ejection fraction for intervention group was improved and found to be 44.39±5.32%. The study had found, patients with reduced ejection fraction had higher rates of co-morbid conditions like diabetes, hypertension and other cardiovascular disorders.

From the datas collected during follow up showed an improvement in health related issues in intervention group due to post discharge home based management.

Findings from results indicates, patients comes under intervention group shows an improvement in functional status and a reduction in the frequency of hospital readmission. During follow-up, the patients in the intervention group were re-admitted less when compared with patients in the control group; specifically, only 40% of patients comes under intervention group were readmitted after intervention. In the case of control it was 47.65%.

Quality life was the major tool used for the measurement of outcome in heart failure patient. Minnesota Living With Heart Failure Questionnaire, (MLWHFQ) was used to measure the Quality of life of the patients included in the study. Patients shows different responses to the questionnaire. The responses mainly depends on the severity of the disease and mental status. Questionnaire consist of 21 different questions. Outcome was measured by dividing the questions in to 3 different domains.

When assessing of quality of life after pharmacist intervention, patients comes under intervention show better outcome compared to control group.

Phamaceutical care helps to decrease the overall score of intervention group (40.10 and 44.40 for intervention and control respectively) with a significants, P= 0.023.

By comparing patients who received intensified Pharmaceutical Care with those who received standard Pharmaceutical Care, we identified several statistically significant differences in the quality of life (QL). By participating in this study the quality of life of the patients in the Intervention Group was stabilized in several subscales indicating that the quality of life can be altered by patient counselling.. In the present study we depicted a clear benefit for the patients' quality of life due to an intensified involvement of pharmacists.

CONCLUSION

Congestive heart failure has become more prevalent and causes, a dangerous burden on the healthcare system. Although the medical community continues to make advances in the treatment of left ventricular systolic dysfunction. Study had shown that the best approach is a teamwork, that includes the physician, a cardiologist specializing in heart failure, and other healthcare providers including nurses, pharmacists, physical therapists, dieticians, and social workers. The findings of this study may help estimating and decision making concerning the utilization of healthcare resources, especially in quality of life and hospitalisation rate.

During assessment of Quality of life, patient's response to the questionnaire depends on the physical and mental status, So the response is not satisfactory. Pharmacist intervention has only a limited effect on health related quality life outcomes in CHF. Although some beneficial effects can be seen in intervention group during follow up. The study indicate the benefits of pharmacist care in reducing hospitalization in patients with HF. Interventions that include some element of pharmacist care, reduced the rates of both all-cause hospitalization, also improved the a patient's compliance to the medication. Pharmaceutical care also improves the ejection fraction in intervention group compared to control.

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