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Impact of focused patient care in clinical outcomes of heart failure patients: A comparative study

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ABSTRACT

The aim of the study was to assess the clinical outcomes like alleviation of symptoms, improvement in lab parameters and cardiac function among heart failure patients treated under Heart Failure clinics and patients consulting in general cardiology outpatient departments (OPD). 200 heart failure patients who consulted Heart failure (HF)clinic and general cardiology OPD's during the year of 2017 who satisfied the inclusion and exclusion criteria were selected for the study. Patients were followed retrospectively and Patient data relevant to the study were obtained at 1st, 6th and 12th months from the electronic medical record (EMR). The data collected were then evaluated for different outcomes and were then compared between the two groups. After 6 and 12 months of treatment dyspnea and chest pain significantly reduced in the HF clinic group compared to other cardiology OPD patients. Dyspnoea and ankle swelling were found to be worsened in patients visiting other cardiology OPD when compared to their previous visit. All laboratory parameters of patients in HF clinic were maintained within the normal range. Clinically significant improvement in blood cholesterol level, LDL, HDL, TG and BP were observed in patients treated under HF clinic. The study concluded that heart failure patients who received personalized care through heart failure clinics had significant improvement in their clinical presentations, laboratory parameters and cardiac function parameters within one year of diagnosis.

INTRODUCTION

Cardiovascular diseases are currently the leading cause of death in India with the incidence of heart failure rising at an alarming rate. [1] Heart failure is marked by frequent exacerbations that leads to increased hospital read missions and mortality.[2] Inspite of the advancement and developments in the treatment of heart failure, the morbidity and mortality rates remain high. Management of heart failure involves many complexities. To address these complexities HF management programs like HF clinics have been introduced. HF clinics are multi disciplinary outpatient based focused approach that aims at management of heart failure specific symptoms, review medications, dose titration, management of heart failure related risk factors, monitoring patient compliance, provision of guideline directed medical therapy and timely follow up of patients. HF clinics have shown a better outcome in terms of hospital readmission, mortality, quality of life and reduction of health care cost [2] in various studies conducted in other countries. However data regarding impact of heart failure clinics from India are lacking. This was the first study in India designed retrospectively to evaluate the improvement in clinical outcomes of heart failure patients receiving specialised care under HF clinic and usual care in other cardiology OPD.

Clinical presentation of heart failure patients includes typical symptoms(shortness of breath and breathlessness), less typical symptoms(nocturnal cough and wheezing), more specific signs like Elevated jugular venous pressure and less specific signs like peripheral edema. [3] Routine laboratory test in heart failure patients include complete blood count, serum electrolyte level, renal function, hepatic function assessment and serum iron levels. [4] Measurement of cardiac function parameters like ejection fraction, blood pressure and serum lipid levels are important in the diagnosis and treatment of heart failure. [5,6,7].The objective of the study was to assess the clinical outcomes like alleviation of symptoms, improvement in lab parameters and cardiac function among heart failure patients treated under Heart Failure clinics

and patients consulting in other cardiology OPD.

METHODOLOGY

The study was carried out in a tertiary care Interventional Cardiology and Cardiac Surgery hospital in Kochi, Kerala. A total of 200 heart failure patients who consulted in HF clinic and general cardiology OPD's of the study site hospital in the year of 2017 who satisfied the inclusion and exclusion criteria were selected for the study. Data collection was done for a period of 10 months extending from August 2018 to April 2019. Heart failure patients aged above 18 years who consulted in HF clinic and other cardiology OPD in the year 2017 and diagnosed with NYHA class1-1V of heart failure were included in the study. Patients who did not satisfy the inclusion criteria and those with incomplete medical data records were excluded from the study. Nearly 250 patients consulted for the first time in HF clinic in the year 2017 and every alternate candidate from the list of 250 patients were selected to be included in the study. Also heart failure patients

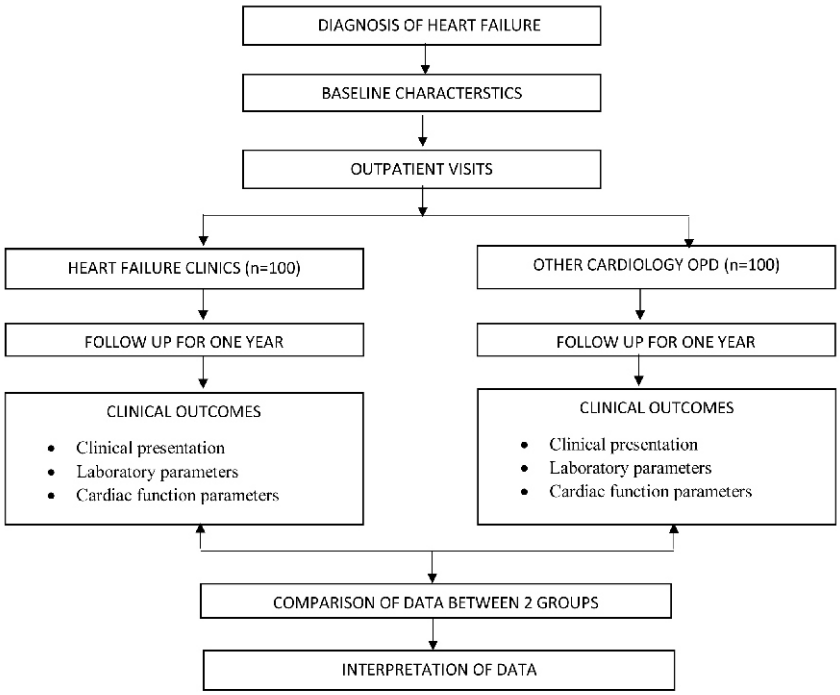

Fig. 1 : Consort flow chart of the study

Table 1 : Comparison of symptoms between patients in HF clinic and other cardiology OPD

Symptoms	1st Month (No: of patients)		p value	6th Month (No: of patients)		p value	12th Month (No: of patients)		p value
	HF Clinic	Other cardiology OPD		HF Clinic	Other cardiology OPD		HF Clinic	Other cardiology OPD	
Dyspnoea	48	40	0.25	3	15	**0.00**	2	22	**0.00**
Wheezing	5	5	1.00	0	2	0.15	1	1	1.00
Pulmonary edema	30	32	0.76	2	7	0.08	6	5	0.75
Palpitation	7	2	0.08	0	0	-	0	1	0.31
Ankle swelling	6	48	**0.00**	0	5	**0.02**	1	12	**0.00**
Cough	5	15	**0.01**	3	4	0.70	1	2	0.56
Chest pain	33	45	0.08	0	6	**0.01**	0	7	**0.00**
Precordial discomfort	1	0	0.31	0	0	-	0	0	-
Numbness of limbs	0	0	-	2	0	0.15	0	0	-
Jugular vp	4	1	0.17	0	0	0.15	2	0	-
Fatigue	3	5	0.47	10	10	1.00	0	17	0.08

HF- heart failure, OPD- outpatient department

who consulted in general cardiology OPD's on Friday's and Saturday's were enrolled. Institutional Review Board and Institutional Ethical Committee of Lisie Hospital, Kochi (Reg no: ECR/40/inst/KL/2013/RR-16) approved the proposed study protocol before the commencement of the study. Patients were followed retrospectively for a period of one year. Patient data relevant to the study were obtained at 1st, 6th and 12th months from the electronic medical record (EMR). Patient data derived from the EMR were then recorded in a pre-designed data collection proforma. The data collected were evaluated and different outcomes were then compared between the two groups. A consort flow chart of the study design is depicted in figure 1.

Statistical analysis

Data storage and analysis were performed using Microsoft Excel 2010 and SPSS Version 24. Independent samplet-test and paired t-test were used for the comparison of continuous variables. All the p values were two-tailed and a significance level of 5% was used.

RESULTS

Demographic details such as age, gender, social habits, risk

Table 2 : Comparison of laboratory parameters between HF clinic and other cardiology OPD

Lab parameters	1st Month		p value	6th Month		p value	12th Month		p value
	HF Clinic	Other cardiology OPD		HF clinic	Other cardiology OPD		HF Clinic	Other cardiology OPD	
Haemoglobin	12.95	14.21	0.37	12.52	12.01	0.08	12.76	12.36	0.18
Sodium	135.90	135.48	0.62	137.71	136.36	0.13	138.64	137.59	0.14
Potassium	4.39	4.45	0.48	4.47	4.40	0.47	4.36	4.58	**0.02**
Creatinine	1.33	1.39	0.51	1.34	1.41	0.37	1.37	1.64	0.25
Urea	37.84	38.57	0.75	37.46	43.13	0.07	37.22	39.07	0.47
Uric acid	5.81	7.27	**0.00**	5.84	5.03	0.12	5.62	6.62	**0.00**
SGOT	214.27	85.96	0.38	186.94	34.56	0.51	78.48	37.40	0.25
SGPT	107.93	56.1	0.22	62.68	43.26	0.57	61.35	24.77	0.31
Bilirubin total	0.69	0.88	0.18	0.60	0.81	0.28	0.57	1.01	0.07
Bilirubin direct	0.52	1.01	0.26	0.42	0.51	0.49	0.39	0.42	0.85

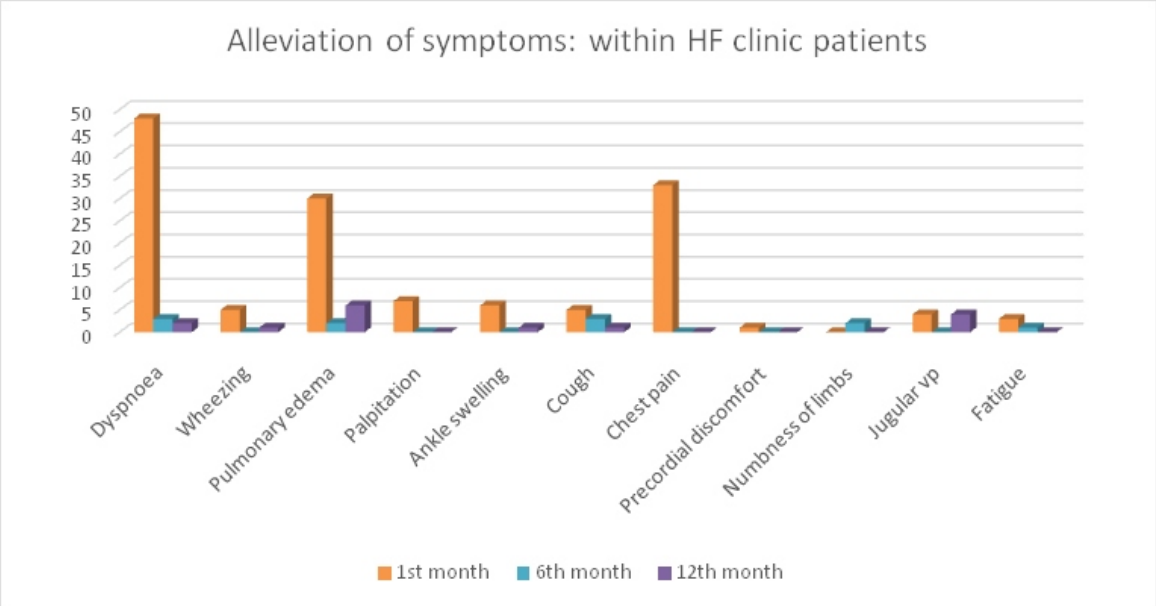

Fig. 2 : Clinical presentation of patients in HF clinic during 1, 6 and 12 month of study

factors and comorbidities were collected from the patient records. A male predominance was observed in both the groups and most of the patients were in the age group of 46-60 years in HF clinic, whereas it is 61-75 years in other cardiology OPD. Mean age of the patients were 60.64±11.44 in HF clinic and 63.62+10.48 in other cardiology OPD. Among their social habits more smokers were reported in HF clinic whereas equal number of alcoholics in both study groups. The most prevalent risk factor was diabetes mellitus (60% HF clinic vs 65% in other cardiology OPD) and the most reported comorbidity was AWMI among the 2 studygroups. (42% in both study groups). All the details were compared between patients approaching HF clinic as well as other cardiology OPD and they were comparable since there exists no significant difference between the groups on their demographic details.

The symptoms experienced by the patients were assessed and found that dyspnoea was the common symptom observed inpatients treated in HF clinic, followed by chest pain. As shown in figure 2, these symptoms were subsided within 6 months and we could see statistically significant improvement for dyspnea ($p<0.00$), pulmonary edema ($p<0.00$), palpitation ($p<0.00$), ankle swelling ($p<0.01$), chest pain ($p<0.00$) and jugular VP ($p<0.04$) when analyzed using Paired samplet-test. These results were also consistent at 12th month, even though some patients experienced

Table 3 : Comparison of Cardiac function parameters between patients of HF clinic and other cardiology OPD.

Cardiac function	1st Month			6th Month			12th Month		
	HF Clinic	Other cardiology OPD	p value	HF clinic	Other cardiology OPD	p value	HF Clinic	Other cardiology OPD	p value
EF	28.84	32.84	**0.00**	35.25	35.511	0.90	38.47	34.35	**0.04**
SYSTOLIC BP	129.24	139.78	**0.00**	128.56	137.15	**0.00**	127.25	135.94	**0.00**
DIASTOLIC BP	79.76	85.61	**0.00**	79.07	82.39	**0.01**	77.72	82.48	**0.00**
PULSE	81.06	89.76	**0.00**	71.66	78.51	**0.00**	70.39	77.35	**0.00**
LDL	93.43	105.9	0.09	79.73	95.16	**0.03**	72.81	94.80	**0.00**
HDL	39.99	44.64	0.08	43.04	42.73	0.90	49.273	43.36	**0.04**
TG	121.29	121.89	0.94	116.31	163.65	**0.00**	103.45	132.12	**0.00**
Serum Cholesterol	151.80	164.35	0.15	137.45	157.75	**0.00**	119.05	154.60	**0.00**

EF-ejection fraction, BP-blood pressure, LDL-low density lipoprotein, HDL- High density lipoprotein, TG- triglycerides

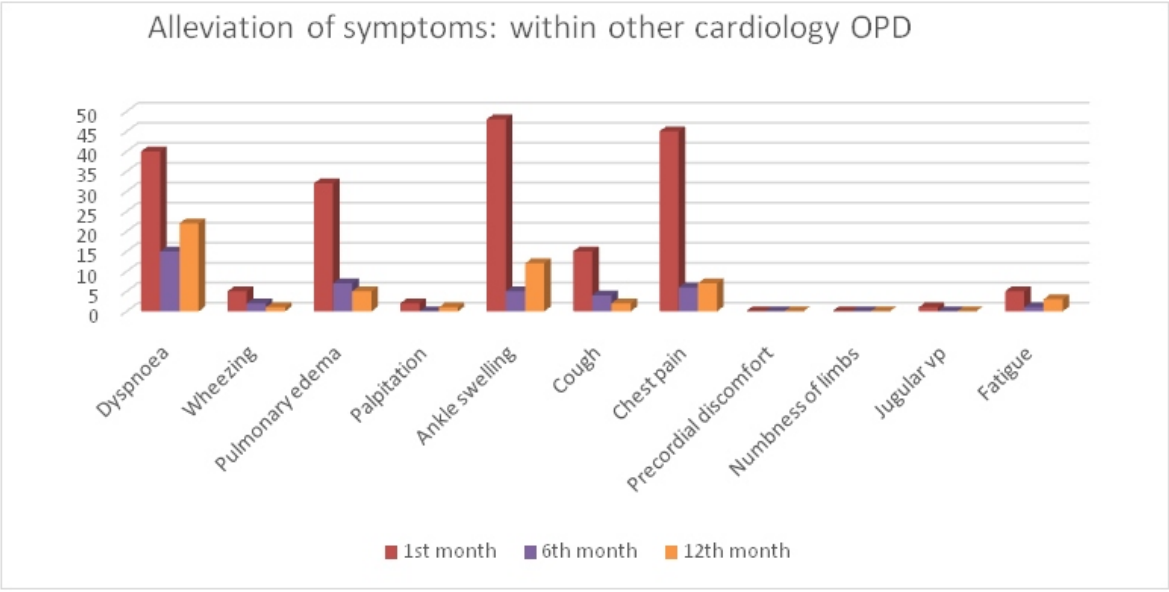

Fig. 3 : Clinical presentation of patients in general cardiology OPD during 1, 6 and 12 months of study

increased JVP ($p<0.15$). Other symptoms such as wheezing, cough, precordial discomfort, numbness of limbs and fatigue were reported only by few patients. The symptoms experienced by patients in other cardiology OPD were almost similar to patients in HF clinic. Figure 3 shows that the most commonly observed symptom was ankle swelling followed by chest pain and dyspnea. During the 6th month visit we could see a statistically significant improvement for symptoms like dyspnea($p<0.00$), pulmonary edema($p<0.00$), ankle swelling($p<0.00$), cough($p<0.01$) and chest pain(0.00). This same trend continued during the 12th month visit but a greater number of patients experienced symptoms like ankle swelling, dyspnea and fatigue when compared to their previous visit. Few patients reported wheezing, palpitation, JVP, but clinically significant difference was not evident. Figure 2 and 3 clearly depicts that management of heart failure through HF clinics had led to a greater extend of improvement in the initial symptoms presented by the patients when compared to those treated in general cardiology OPD. Data from both arms of the study were then compared to confirm if focussed care in HF clinic had an impact on reducing the symptoms initially presented by the heart failure patients. Table 1 shows that no symptoms except ankle swelling and cough had statistically significant difference in clinical presentation between the groups. After 6 and 12 months of treatment dyspnea and chest pain significantly reduced in the HF clinic group compared to other cardiology OPD. Dyspnoea and ankle swelling were found to be worsened in patients visiting other cardiology OPD when compared to their previous visits.

Effect of treatment on lab parameters like Haemoglobin, electrolytes, renal and hepatic function were compared at different time interval in the HF clinic patients. Significant difference in improvement was observed in sodium and bilirubin level. All the other parameters except SGOT/SGPT were within the limit from the baseline onwards. The mean value of SGOT and SGPT levels were elevated in HF clinic and was because a patient had abnormally high value (12230 IU and 3350 IU) which affected the mean value of the studygroup.

On comparing 1st and 6th month visit, it was seen that SGOT had a significant improvement and only sodium exhibited significant improvement on comparing 1stand 12th month visits. Blood levels of creatinine and direct bilirubin were found to be elevated during the 12th month visit when compared to the initial values and might be due to some sort of renal and liver abnormality. Usually in HF clinic dose adjustments are made based on patient's lab parameters and is made easy due to repeated visits. But as the frequency of visit in other cardiology OPD is less, it makes it difficult for the physician to make dose adjustments.The baseline lab parameters among HF clinic patients and other cardiology OPD patients revealed that except uric acid value, no significant difference existed between the groups. As shown in table 2, during 6th month follow up, there was not much difference in these groups. But after one year, other cardiology OPD patients showed significant elevation in potassium and uric acid. Increased levels of creatinine and bilirubin total indicated renal and hepatic dysfunction in other cardiology OPD patient, which was clinically significant.

Ejection fraction or EF is considered as the major predictive factor of cardiac function. Improvement in EF within 6 months of treatment was clearly visible from the analysed data and a considerable improvement in EF was attained within a year of diagnosis. Other parameters like pulse, LDL, HDL and serum cholesterol had statistically significant improvement when comparing 1st and 6th month visits. All cardiac parameters had significant improvement during the 12th month visit and blood pressure was maintained within the normal range throughout the study period. Significant improvement was shown by other cardiology OPD patients in diastolic BP, pulse and LDL cholesterol during their 6th and 12th month visit. Though ejection fraction slightly improved during the 6th month visit, it was found to be decreased at the end of one year. Table 3 showed that significant difference existed for EF, BP and PULSE between patients in HF clinic and other cardiology OPD. BP was found to be in the normal range for HF clinic patients whereas EF was better for other cardiology OPD patients. No significant difference was shown for the cholesterol level between the groups at the baseline. Though there was no statistically significant difference in EF between patients in HF clinic and other cardiology OPD after 6 months of treatment, the improvement with regard to the previous value was better in HF clinic. Significant difference exists for BP, pulse and cholesterol levels except HD Llevel. All cardiac parameters exhibited significant difference during the 12th month of follow up when compared between patients in HF clinic and other cardiology OPD. The value of EF dropped in patients in other cardiology OPD whereas in HF clinic there was significant improvement when compared to the previous visit. The HDL and serum cholesterol showed clinically significant improvement in HF clinic when compared to the other study group.

DISCUSSION

A retrospective study design was developed and initiated to assess the impact of provision of patient focussed care to heart failure patients through a dedicated heart failure clinic. To our knowledge this study was the first of its kind to assess the clinical outcomes of heart failure patient management in a heart failure clinic. The study results brought out the fact that management of heart failure patients in a heart failure clinic was associated with significant improvement in their clinical outcomes like alleviation of signs & symptoms, improvement in upnormal laboratory parameters and normalisation of irregular cardiac function parameters. Classical symptoms like dyspnoea, chest pain and ankle swelling were remarkably improved in heart failure patients within one year of treatment under the heart failure clinic. All cardiac function parameters assessed during the study exhibited both statistical and clinical improvement within a year of heart failure clinic consultation. Till data only limited number of comparative studies on impact of heart failure clinics had been done in India. Hence comparative studies on clinical outcomes of heart failure patients were limited.

Monitoring the signs and symptoms presented by a heart failure patient is important in the diagnosis and evaluation of response to the treatment being given. If the patient presents with the same signs and symptoms, additional therapy has to be given. [8] Several articles had shown the sensitivity and specificity of symptoms in the diagnosis and treatment of heart failure. The classical signs and symptoms of heart failure includes dyspnea, orthopnea, nocturnal dyspnea fatigue, edema, abdominal distention, right hypochondrial pain, tachycardia, pedal edema, increased jugular venous pressure, and abnormal lung sounds [9] Recurrent occurrence of heart failure associated symptoms are associated with decreased quality of life, increased episodes of re-hospitalisation and mortality. [10] Our study was successful in proving the impact of heart failure clinics in improving the classic

symptoms of heart failure. Heart failure clinic group had a lower incidence of recurrence of symptoms. It was clear that provision of personalized care and individualized drug therapy through HF clinics resulted in significant improvement in patient symptoms such as dyspnea, pulmonary edema, palpitation and chest pain. Patients who received usual care under general cardiology OPD exhibited recurrence and worsening of symptoms during the study period.

Increased blood urea nitrogen, creatinine, heartrate, lower systolic pressure and serum sodium and monitoring of renal dysfunction, hemodynamic instability, high levels of Pro-BNP, hyponatremia and presence of co-morbidities are considered as predictors of heart failure. [3] A community study showed that anemia was present in more than half of the heart failure patients and more prevalent in patients with preserved ejection fraction and was a leading cause of mortality. [11]All these evidences point towards the fact that observation and management of all heart failure related laboratory parameters is of prime importance in improving the treatment outcomes of heart failure patients. Our study observed that all laboratory parameters of patients in HF clinic were maintained within the normal range but patients in general cardiology OPD experienced a lower Haemoglobin level during their 6th month visit. An increase in serum creatinine >50% with in 7days was considered as a biomarker of CKD. The mean creatinine level was above the normal range in patients visiting general cardiology OPD when compared to patients in HFclinic.

Multiple studies have proven the efficacy of Beta blockers, ACEIs /ARBs, and MRAs on reverse remodeling and improvement in LVEF. [12] Analysis of our data had shown significant improvement of EF in patients treated under HF clinic when compared to worsening EF in other study group. Epidemiological studies have shown that hypertension, rheumatic heart disease, high cholesterol level, higher levels of LDL and obesity are factors that lead to cardiovascular diseases. [13] Though high cholesterol levels are directly related to the development of cardiovascular diseases, studies which directly relates cholesterol levels to heart failure are limited. Clinically significant improvement in blood cholesterol level, LDL, HDL and TG were observed in patients treated under HF clinic. Several studies had established hypertension as an independent risk factor for heart failure. Another prospective study found a positive relation between systolic blood pressure BP and HF. [14] In our study we observed significant improvement of systolic BP within the 6th month visit and was maintained within normal in patients under HF clinic. Within a year of patient management in HF clinic, all cardiac function parameters exhibited both clinically and statistically significant improvement. Thus patient focussed care provided through Heart failure clinics resulted in significant improvement in the clinical outcomes of heart failure patients.

LIMITATIONS

Study limitations comprised of the retrospective design being adopted for the study and restriction of study location to a single center. This study could have been extended to a larger population from multiple heart failure clinics to produce a more generalized result.

SCOPE IN FUTURE

Personalized care will be the future of health sector and hence extending this study into other specialized care clinics could generate valuable results. Adoption of a prospective study design and evaluation over multiple heart failure clinics could contribute more towards the role of a clinical pharmacist. The present Indian setting serves as a platform for blooming up of specialised clinics with multi disciplinary approaches with more involvement of a clinical pharmacist that can contribute to better patient care and hence produce better healthcare outcomes.

CONCLUSION

Provision of patient focussed care to heart failure patients through heart failure clinics resulted in significant improvement in clinical outcomes including alleviation of presenting signs and symptoms, laboratory parameters and cardiac function parameters within one year of presentation in the heart failure clinic. The ameliorated clinical outcomes of the heart failure patients are attributed to the patient focussed services provided in the heart failure clinic which included identification and management of heart failure specific symptoms, review medications, drug dose titration, management of heart failure related risk factors, monitoring patient compliance, provision of guideline directed medical therapy and timely follow up of patients.

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CONFLICTS OF INTEREST

All authors have none to declare.

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