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Clinical Profile in Refractory Heart Failure and Its Outcome in Rural Institutional Setup

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***ABSTRACT**--Refractory HF can be defined as "the persistence of symptoms that limit daily life (functional class III or IV of the New York Heart Association [NYHA]) despite optimal previous treatment with drugs of proven efficacy for the condition." This is very challenging to manage and so disease is associated with poor quality of life and high mortality rates. This study has been planned to see the clinical profile like etiology, clinical features and prognosis as studies regarding this in India is lacking.To study clinical profile of refractory heart failure in rural tertiary care hospital.To identify aetiology of refractory heart failure in rural population.To study the outcomes as duration of ICU stay, discharge and death.To compare the outcome in different gender and Body mass index status.In this cross sectional study, 40 patient were enrolled and diagnosed on the basis of criteria for refractory HF (European Society of Cardiology). Patient were admitted in Medicine department from October 2018 to January 2020.20(50%) patients had coronary artery disease, 18(45%) patients had cardiomyopathy, 22(55%) patients had acute or history of myocardial infarction. 6MWT was done in all patients (excluding patients who had contraindications). Total of 14(35%) patients had <300 meters walk on admission. 20(50%) patients had LVEF less than 20%. Total of 8(20%) patients had died in hospital.Refractory Heart Failure is associated with very high mortality rates. Hence screening the patient for etiology is very important. Early intervention and treatment of etiology can prevent further consequences of the disease.*

***Keywords**--Refractory, Heart Failure(HF), Clinical profile, prognosis*

I. INTRODUCTION

Heart failure (HF) can be defined by "the inability of systemic perfusion to meet the body's metabolic needs and is caused by failure of heart to pump adequately". HF can be divided into diastolic and systolic HF. Systolic failure is caused by reduced cardiac contractility whereas diastolic failure is impaired cardiac relaxation with ventricular filling impairment. HF results from structural or functional congenital or acquired cardiac disorders that impairs cardiac function.**(1)**

Heart failure (HF) poses a major health problem in India as post admission mortality ranges from 20% to 30%. **(2)**

Few studies indicate that more than half patients diagnosed with HF tend to have a normal or near normal EF.**(3)** This clinical condition is known as "heart failure with normal ejection fraction" (HFnEF) or "diastolic heart

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failure" (DHF). Mechanism of DHF includes abnormal left ventricular filling, impaired LV relaxation and elevated filling pressure. Also recently many new treatment modalities are made in the management of systolic heart failure (SHF), the mortality rate remains high. In comparison, trivial progress has been made in the treatment of DHF. The mortality rates because of DHF is about the half that of SHF.**(4)** Most common risk factors associated with HF in India includes hypertension, diabetes **(5-11),** obesity **(12) (13)**,Rheumatic heart disease and coronary artery diseases (CAD). **(5)**

Factors that worsen prognosis in HF includes Atrial fibrillation (AF), Chronic kidney disease (CKD) and few others like hyponatremia, raised levels of Type B Natriuretic Peptide (BNP), chronic lung disease and repeated hospitalization. AF affects nearly 20% to 30% of patients with HF. **(6-9)**

Refractory or advanced HF can be defined as "the persistence of symptoms that limit daily life (functional class III or IV of the New York Heart Association [NYHA]) despite optimal previous treatment with drugs of proven efficacy for the condition, i.e. ACE inhibitors, angiotensin II receptor antagonists (ARA-II), diuretics, digoxin, and beta-blockers". **(10)**

ACC/AHA proposed a classification in which Refractory HF relates to stage D HF. "This refers to patients with advanced structural heart disease and severe signs of HF at rest who are candidates- in the absence of contraindications-for other specialized interventions, such as heart transplantation (HT), ventricular remodelling, implantation of mechanical assistance devices or the administration of intravenous inotropic drugs." Terminal HF is the term that consists of "a very poor response to all forms of treatment with poor quality of life and frequent hospitalization and life expectancy no more than 6 months" **(11)**

Exercise intolerance is a key feature in HF that is of great importance as far as prognosis is concerned. Its precise quantification is important for studying pathogenic mechanisms and severity of HF **(14)**

6MWT (six minute walk test) is "a measure of distance, which is considered submaximal and perhaps more closely approximates the capacity to perform activities of daily living." **(15)**

It is safe and simple method performed without the need of any equipment. Also, it meticulously allows us to predict hospital admissions due to HF and mortality risk in patients with poor LV function. Results have shown that the mortality was three and half folds more in patients who covered less than 350 meters than in those who could walk over 450 meters in the Studies of Left Ventricular Dysfunction (SOLVD) registry sub study. **(16)**

The test is independent predictor of mortality in HF **(17)**

II. BACKGROUND/RATIONALE

Refractory HF can be defined as "the persistence of symptoms that limit daily life (functional class III or IV of the New York Heart Association [NYHA]) despite optimal previous treatment with drugs of proven efficacy for the condition like ACEI/ARB's, Beta blockers, Diuretics, ARNI's". This is very challenging to treat and so disease is associated with high morbidity and mortality. This study has been planned to see the clinical profile like etiology, clinical features and prognosis as studies regarding this in India is lacking.

III. OBJECTIVES

A) To study cause of heart failure in rural population - hypertension, coronary artery disease, rheumatic heart disease, cardiomyopathy, primary pulmonary hypertension and other non-cardiac causes like anaemia, thyrotoxicosis, Chronic kidney disease.

B) Prognosis and outcomes in refractory heart failure patients.

IV. METHODS

Study design*:* Observational cross sectional study.

Setting*:* The study will be conducted in the Acharya Vinoba Bhave Rural Hospital (AVBRH), a tertiary care teaching Hospital, situated in the rural area of Sawangi (Meghe) Wardha, in Central India.

Participants:

INCLUSION CRITERIA*:* Inclusion of patients as per the europeon guidelines for refractroy heart failure.

EXCLUSION CRITERIA*:* Pregnancy, coronary artery disease with good LVEF, severe anemia (hemoglobin <8.00 g/dl), ventricular pacemaker, patients not giving consent.

All the patient of heart failure will be selected at screening. Later, those patients who falls in group of refractory heart failure criteria will be selected for further studies. Patient will good LVEF will be excluded. All the patients will be followed up after 1 month from the date of discharge. Any patient not giving consent or doesn't wish to participate will be excluded.

Bias: No bias.

Study size: $n=Z_{\alpha/2}{}^2 * P * (1-P) / d^2$

$Z_{\alpha/2}$ is the level of significance at 5% i.e. 95% confidence interval = 1.96

P = prevalence of Refractory heart failure 1.2% = 0.012

d = Desired error of margin = 3% = 0.03

n = 1.962 X 0.012 X (1- 0.012)/0.032

n = 50.60 = 55 patients needed in the study

A sample size of 55 was taken based on above mentioned formula.

V. STATISTICAL METHODS

Descriptive statistics will be used and the data will be presented as mean standard deviations and percentage/proportions.

VI. EXPECTED OUTCOMES/RESULTS

Patients of refractory heart disease had either of the following as aetiology. The common causes include coronary artery disease, cardiomyopathy, acute or history of myocardial infarction, hypertension, dyslipidaemia and diabetes. 6MWT will be used as a prognostic marker of the condition. A distance of less than 300 meters is indicative of poor prognosis. All patients with EF of less than 20% tend to have poor prognosis and has a high mortality rate. Arrhythmias also carry a risk of high mortality.

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VII. DISCUSSION

Vakil in 1949 had reported the epidemiology of HF in India describing it to be coronary and hypertension (31%), Rheumatic heart disease (29%), infective(mostly syphilitic (12%), and pulmonary (9%) as the common causes in 1281 patients hospitalized and diagnosed to have HF. The scenario presently is completely different.**(21)**

Mendez and Cowie, in 2001 found that no population based Heart failure study have been ever done in all developing countries,**(19)** making it difficult to predict global prevalence of HF. The WHO Global Burden of Disease study have placed HF in multiple categories within cardiovascular disease that includes ischemic, hypertensive, RHD and inflammatory.**(20)**

In the Framingham Heart Study, the overall incidence of HF due to obesity defined as body mass index [BMI] of >30 kg/m2 has been expected to increase by 0.5% in men and by 0.3% in women, after adjusting age, left ventricular hypertrophy, hypertension, valve disease, myocardial infarction, diabetes and hypercholesterolemia.**(22)** Reddy and his colleagues estimated the prevalence of obesity to be 6.8% considering BMI greater than 30 kg/m2 in 10 970 participants from urban part of Delhi and rural part of Haryana in 2002. **(23)**

In a study conducted on admitted patients of Heart Failure (as per Framingham criteria) from South India, 94 consecutive patients having age >60 years were studied over a time period between 2003 to 2005.**(35)** Mean age was 69 years and 54% were males. The etiology being CAD (55%),valvular heart disease (13%), dilated cardiomyopathy (10%), and heart disease secondary to hypertension (6%). No etiology was found in 12% of all patients. 22% patients had had a past history of MI. 23% patients had HF with normal EF (EF >50%). **(36)**

The prevalence of hypertension has been on rise than before and is estimated to increase by 50% by 2025 in comparison with prevalence in 2000.**(24)** If the overall incidence of HF in hypertensive patients with a systolic blood pressure (SBP) of 144–154 mmHg is 0.1 - 0.6%, as reflected in the Hypertension Optimal Treatment (HOT) **(25)** then the total number of new HF cases may show an increment of 50% approximately by the year 2025. Similarly, the prevalence of diabetes is projected to increase by 50% 2025 in India from that in 2000.**(27)** HF incidence increases 5 folds in patients with HbA1c >11.9% in comparison to a patient with HbA1c <6% as shown in UKPDS trials. **(26)**

RHD has always been a major heart disease in India, having prevalence of 1.0–5.4 cases per 1000 schoolchildren in one study. **(28)** Grover *et al*. did a community based study in rural Punjab with a follow-up of 3 years among 32 patients with chronic Rheumatic Heart Disease at baseline after screening a population of 114,610. 3 patients had died (~10%) due to progressive HF symptoms, largely due to poor compliance to treatment and poor socioeconomic status. Thus, the prevalence of significant HF in RHD is approximately 20–30% of the total burden with an overall annual mortality rate of about 3%. This can be largely prevented and controlled by corrective procedures carried out like valvuloplasty/valve surgeries which are not carried out owing to financial issues. **(39)**

Xavier *et al*. in the India-based CREATE ACS registry had evaluated the association between Acute Coronary Syndrome care and socioeconomic status (SES).**(30)** Patients with a lower SES had less likelihood to undergo CAG, PTCA and CABG and were less likely to get adequate treatment for CAD. These differences in socioeconomic status contributes significantly to 30-day mortality as seen in the poor SES compared to richest

stratum. Lack of empowerment, poverty and healthcare inequalities are likely to increase the incidence and prevalence of HF in India. **(31)**

The Trivandrum HF registry (THFR) enrolled 1205 consecutive admissions using the "European Society of Cardiology 2012 criteria" for enrollment. The mean age was 61.2 years with most common etiology being IHD (72%). **(32)**

Chaturvedi and Seth *et al*. have tried to estimate incidence and prevalence of HF in India. Adults of six villages from North India were screened, and cases of breathlessness for atleast 6 months were identified by trained health workers. 10,163 cases were screened, chronic breathlessness was present in total of 128 (1.3%) patients. The prevalence of HF was estimated to be 1.2/1000 in the screened population.**(33)**

The AFAR STUDY: The study was done on 90 patients with mean age of 53.5 years (± 17.7). Majority of patients were men (63.0%) with poor LV systolic function. The most common causes of HF in this study were ischemic cardiomyopathy (53.9%), dilated cardiomyopathy (18.5%), and rheumatic heart disease (10.8%). In-hospital mortality was very high (30.8%) with cause being progressive HF (92%), and the rest 8% were due to arrhythmias (6%) and renal failure (2%). Post discharge major adverse event rates including death and even re-hospitalization were 27.3% and 38.1% at 1 month and 6 months, respectively. They had suggested that the maximum events occurred within 3 months following discharge. **(34)**

Jose and Gupta *et al*. studied data from a large tertiary hospital to associate the 30-day HF rate with ST elevation MI (STEMI) in 1320 consecutive patients. They found HF in 5% of these patients**(37)**

In the CREATE-ECLA study from India a total of 8060 amongst 20,201 participants had the 30-day HF. The rates of development of HF were approximately 17% and 30-day mortality was 10%.**(40)** In another cross-sectional study done on 120 consecutive patients with ST Elevation MI presenting to tertiary care hospital in central India, the 30-day HF rate was approximately 2% for the age of 60 years or below and 9% for age of >60 years; 30-day mortality rates were 12.5% and 39%, respectively.**(41)** The OASIS 2 registry studied the outcomes of non-ST elevation (NSTE) acute coronary syndrome (ACS). A total of 1028 patients were enrolled from India.**(42)** The mean age was 57 years and 42% patients had a past history MI. The prevalence of HF was 7.2% at baseline that is less in comparison to 11.5% in developed nations where the mean age of presentation was 64 years. The CREATE registry also investigated the outcomes in >20,000 patients admitted all over India with ACS. **(38)** History of HF was present in 1.6% (2.8% in those with NSTE-ACS and 0.8% in those with STEMI).

Also a number of articles associated with factors and conditions of the study were reviewed (43-80).

Limitations: Financial constraints

Generalizability***:*** this study has been conducted over a small population. Hence it cannot be generalised to community.

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