

THE IBADAN ACUTE AND CHRONIC HEART FAILURE PROJECT: RATIONALE AND DESIGN

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ABSTRACT

Introduction: Until recently, little was known about the emerging problem of non-communicable forms of heart failure supplementing traditional pathways to the syndrome in sub-Saharan Africa due to infections and infestations. Contemporary studies have built on historical reports to demonstrate that the aetiology and indeed case profile of heart failure (i.e., more women and younger individuals affected in the prime of their lives) is different from that of high-income countries.

Objective: This study will assess the long-term outcomes, risk factors, clinical phenotypes, and genomics of heart failure in Ibadan, Nigeria, estimate the healthcare cost associated with heart failure and how it affects evidence-based care, and understand the cultural and social conceptions of heart failure in the city and, by extension, in Nigeria.

Methodology: Data from each subject shall be obtained using a uniform and standardized case report form. A detailed clinical documentation on cases of heart failure will be undertaken. The following data shall be obtained: study identification number, centre code, demographic data, date of diagnosis of HF, and pre-admission history (previous heart failure-related admissions). Others include New York Heart Association functional class, symptoms, signs, self-reported cardiovascular risk factors, aetiology of heart failure, comorbidities, blood investigations, point-of-care biomarker, Chest X-ray, 12-lead ECG, echocardiography, medications, barriers to care, quality of life data, etc. Blood samples will be obtained during enrollment for analysis of biochemical biomarkers.

Results: The primary outcome of the study will be mortality by any cause. Secondary outcomes will include non-fatal major events (both resulting in and not resulting in admission).

Conclusion: The project will provide data on the contemporary aetiology, clinical profile management and outcomes of heart failure in Ibadan, which may be extrapolated to other parts of the country.

Keywords: Heart failure, Cardiac failure, Epidemiology, Outcome, Ibadan, Nigeria

INTRODUCTION

Heart failure (HF) has emerged as a major global public health problem.¹ The syndrome is now an issue of global importance. It has been established that the burden of HF doubles with each passing decade after the age of 40 years due to the aging population and increasing burden of risk factors, including hypertension, diabetes mellitus, ischaemic heart disease, and, more recently, obesity.²

Heart Failure affects over 64 million people worldwide.¹ It is a highly symptomatic syndrome that

affects 2-3% of the population in high-income countries, especially in people above the age of 65 years.³⁻⁵ Approximately 15 million (out of 900 million) Europeans and 5.8 million (out of 300 million) Americans are affected by HF.^{6,7} In the United States of America (USA) alone, up to 2.4 million hospital admissions can be attributed to HF as primary or secondary diagnoses.⁸ It is the primary reason for 12-15 million office visits and 6.5 million hospital days each year.⁸ About 670,000 new cases occur in the USA yearly.⁸

Data from developed countries show that half of HF patients are hospitalized within 6 months of discharge, and 70% of these are due to worsening of previously diagnosed HF.⁹ Jencks *et al.*¹⁰ showed that HF is the number one reason for readmission in the USA. Heart failure readmission is associated with higher mortality compared to the index admission. Heart failure-related admissions and re-admissions have been projected to rise in the coming years due to the aging of the world population. By 2050, 1 in 5 Americans will be elderly, and 80% of patients hospitalized for HF in that country are usually above 65 years.⁸ Heart failure is associated with shorter life expectancy, greater morbidity, and impaired quality of life than most common diseases.¹¹ About 30% of people die within 3 months of diagnosis of HF.^{12,13} Annual mortality is 10% thereafter.^{12,13} In high-income countries, the economic burden of HF is high because it is associated with frequent hospital admissions.^{12,13} Moreover, management of HF places a significant financial burden on patients, their families/caregivers and, as indicated, society as a whole.^{12,13} Over 39 million dollars is spent annually in the USA for the care of HF patients.¹¹ In Europe, over 60% of the economic cost of HF is related to hospital admissions.¹¹ This is because HF is associated with high rates of hospital admissions, readmissions, and frequent clinic visits.¹¹ In response, strategies for the effective management of the disease in the outpatient setting have been developed and applied. This has led to improved survival in some countries.^{6,14,15}

Cardiovascular diseases are increasingly being recognized in Africa as a result of increased aging among the population, as well as better strategies aimed at the control of communicable diseases and malnutrition.¹⁶ A rapid epidemiological transition has been observed in sub-Saharan Africa (SSA), with an increased prevalence of cardiovascular risk factors such as hypertension, diabetes mellitus, hyperlipidemia, and obesity.¹⁶

Until recently, little was known about the emerging problem of non-communicable forms of HF supplementing traditional pathways to the syndrome in SSA due to infections and infestations. Contemporary studies from South Africa¹⁶ and Nigeria⁽¹⁷⁾ have built on historical reports to demonstrate that the aetiology and indeed case profile of HF (i.e. more women and younger individuals affected in the prime of their life) is different from high-income countries. As such, HF is now responsible for 7-10% of medical admissions in the region.^{17,18}

These are entirely based on studies on acute HF. There are few data on chronic HF in Africa. Furthermore,

the nexus between endemic infections such as tuberculosis (TB) and HIV/AIDS and other non-communicable or non-infectious risk factors and HF in Africa is scarcely documented.

Gaps in knowledge on heart failure in sub-Saharan Africa

Co-morbidities in HF patients, which are common and important to outcomes, have not been well studied in large cohorts in SSA. In addition to this, the role and co-occurrence of infections such as tuberculosis and HIV/AIDS have not been extensively explored in the region. There is a paucity of information on the long-term outcome of HF in SSA (rehospitalization and mortality) and current phenotypes of HF (HF_rEF, HF_pEF, HF_mrEF), their clinical and sociodemographic predictors, management, and outcomes are not well described in the region. There is also a paucity of data on the assessment of barriers to HF care.

There is also a paucity of data on cultural and social conceptions of HF, and there are only a few genetic and genomic HF studies in SSA in general and Nigeria in particular.

We do not know to what extent standard care pathways and evidence-based treatment algorithms are applied in the management of HF, and we also do not know to what extent high out-of-pocket expenses contribute to low levels of treatment. Furthermore, we do not know the scope of quality improvement to address poor outcomes and reduce HF-related mortality in Nigeria.

Significantly, given its enormous potential cost implications (both related to direct health care costs and economic burden on affected individuals and their families), there are very few data on the economic burden of HF in SSA. Although there is existing evidence of economic cost and impact from the Abeokuta HF registry, data on healthcare spending linked to chronic HF care from a household perspective are lacking. In addition, the extent to which out-of-pocket costs (drugs and consultations/admissions) act as a barrier to continuing evidence-based care is not available. Lastly, the extent patient-centred approaches (their values and preferences) are applied to care plans in Nigeria is not available. The use of patient-reported outcome measures in routine care (PROMs) has not been explored.

Aim

The primary objective of this study is to assess the risk factors, clinical phenotypes, genomics, and long-term outcomes of HF in Ibadan, Nigeria.

Objectives

The objectives of the study include: to define the clinical profile of heart failure in Ibadan, Nigeria, to determine the short-term, medium-term, and long-term outcomes of heart failure in Ibadan and by extension in Nigeria; and to identify comorbidities (infections and non-infections) in heart failure in Nigeria and the clinical implications.

In addition, the study hopes to develop predictive models of mortality, rehospitalization and complications associated with HF; estimate the healthcare cost of HF; develop a community engagement and education programmes on non-communicable diseases (NCDs); explore the cultural and social conceptions of HF as well as investigate genetic associations of ACE, LMNA and Troponin T (TNNI2) variants with HF in the study population.

It also intends to explore the extent standard care pathways and evidence-based treatment algorithms are applied in the management of HF, and use data from this to explore the feasibility for quality improvement; investigate the extent high out-of-pocket expenses contribute to low levels of treatment for HF; and finally develop capacity through mentorship and academic degree programmes

METHODS

Study design

The Ibadan Acute and Chronic Heart Failure Project shall be a pragmatic, real-life, prospective study. Subjects with acute and chronic HF will be recruited and followed up. The study has been formally registered (<https://clinicaltrials.gov/study/NCT05936957>).

Study location

The study shall be conducted at the University College Hospital, Ibadan, Nigeria. The University College Hospital, Ibadan, is the oldest teaching hospital in Nigeria and is affiliated with the University of Ibadan. Currently, the hospital has over 950 bed spaces and 163 examination couches, and a current bed occupancy rate of 55-60%. The hospital has over 60 clinical departments. It serves a population of over three million people and receives referrals from all over the country and as well as from the West African sub-region.

Inclusion and exclusion criteria

Subjects are eligible to participate if they are 18 years and older and have clinically and echocardiographically confirmed HF. Subjects who refuse to participate in the study shall be excluded. In addition, those considered unreliable by the investigator concerning

the requirement for follow-up visits shall be excluded. Pregnant women shall also be excluded.

Data collection and case definition

Consecutive HF patients shall be recruited. All eligible patients shall have an echocardiography to confirm the diagnosis. Recruitments will proceed using strategies to facilitate enrolment of consecutive patients at all times, daily, till the sample size is reached. Active recruitment shall be carried out in the first 24-36 months of the study. This shall be extended if we do not meet the target number of patients

Data from each subject shall be obtained using a uniform and standardized case report form (CRF). (See supplementary file). A detailed clinical documentation on cases of HF will be undertaken. The following data shall be obtained: study identification number, demographic data, date of diagnosis of HF, and pre-admission history (previous heart failure-related admissions). Others include NYHA functional class, symptoms, signs, self-reported cardiovascular risk factors, aetiology of HF, comorbidities, blood investigations, Chest X-ray, 12-lead ECG, echocardiography, medications, barriers to care, quality of life data etc.

There shall be active sensitization of cardiologists, family physicians, and outpatient departments on the project so that HF patients can be referred for evaluation.

Research assistants will be recruited, and they will be responsible for evaluating the CRFs for completeness before submitting them to the research database. Generic names for concomitant medications would be recorded in the CRFs wherever possible.

Case definition

The European Society of Cardiology guideline shall be employed for the diagnosis of HF. All cases shall be confirmed at echocardiography. All the echocardiograms shall be performed by trained personnel. For the various forms of HF, Table 1 shows the diagnostic criteria for the aetiological risk factors that shall be employed.

Blood Collection and Testing

Blood sample will be obtained during the enrollment visit for analysis of biochemical and haematological analysis. Where possible biomarker such as NT-Pro-BNP, B-type Natriuretic Peptide, C-reactive protein shall be assayed as well as markers of neurohormones and genetic variants regulating neurohormones. Additional markers specifically related to HF will be measured if such markers are identified in ongoing

Table 1: Case definitions/diagnostic criteria of aetiologic risk factors

s/n	Case	Definitions
1	Hypertensive HF	Shall be diagnosed if there is a previous history of hypertension or sustained BP of >140/90 mmHg in the presence of symptoms of HF, increased LV mass, LV systolic and/or diastolic dysfunction. ¹⁹⁻²¹
2	HF due to valvular heart disease:	
	a. Mitral stenosis	Presence of thickened and calcified mitral valve leaflets, loss of the classic M-shaped pattern of a normal mitral valve, diastolic doming and restriction of the mitral valve leaflet motions.
	b. Mitral Regurgitation	Poor coaptation of the mitral valve leaflets in systole, thickened leaflets, dilated and hyperdynamic left ventricle.
	c. Aortic stenosis	Presence of calcified aortic valve, reduction in aortic cusp separation, highly echo-reflectant aortic valve leaflets
	d. Aortic regurgitation	Poor coaptation of the aortic cusps in diastole, dilated left ventricles, and fine fluttering of the anterior mitral valve in diastole. ^{22,23}
3	Dilated cardiomyopathy	Shall be diagnosed when there are dilated heart chambers with normal or decreased wall motion as well as impaired LV systolic function. ^{24,25}
4	Endomyocardial fibrosis (EMF)	Shall be documented in the presence of clinical features coupled with dilated atria and thickening of the endocardium, especially at the apices of the ventricles. ²⁶
5	Pericardial effusion	It shall be diagnosed when there is echo-free space between the visceral and parietal pericardium. Diagnosis of constrictive pericarditis shall be based on standard criteria. ²⁷
6	Cor-pulmonale/ right heart failure	Shall be considered present when there is a dilated and hypertrophied right ventricle (RV), evidence of increased RV systolic pressure (D-shaped LV in diastole (diastolic flattening of the LV septum)). ²³
7	Ischaemic cardiomyopathy	HF associated with the diagnosis of myocardial infarction. Diagnosis of MI shall be based on ECG changes, cardiac enzyme elevation, and regional wall motion abnormality at echocardiography and/or coronary angiography. ²⁸
8	HF functional profile	HF with reduced ejection fraction (EF) (HFmrEF), HF with mildly reduced EF (HFmrEF), and HF with preserved EF (HFpEF) shall be diagnosed according to standard criteria. ^{29,30}

research in this field and will become available before completion of the study analyses. Patients who specifically consent to participate in genetic analyses will have an additional sample collected for future analysis of genetic markers related to HF. All the laboratory investigations will be carried out at the University College Hospital Central Laboratory.

Follow-up

Follow-up of subjects shall be through clinic visits or via telephone. Telephone numbers of the next of kin of patients shall also be obtained. Information that shall be obtained during the follow-up period shall include, amongst others: well-being of the patient, symptoms, signs, medications as well as events such as readmission, deaths, etc.

Deaths shall be recorded, and their cause shall be ascertained by the review of various source documents or verbal autopsy (“an interview-based method used to determine the likely cause of death for individuals

who died without a medical examination, typically in communities where formal civil registration and vital statistics systems are underdeveloped”) to classify the cause of death.⁽³¹⁾

We shall obtain information on morbidity through local review of hospitalizations, new diagnoses, and interventional or surgical procedures. Further information will be obtained by contacting the patient’s physicians or next of kin (at least the contact addresses and telephone numbers of 2-3 of the next of kin shall be obtained) Details of the patient’s home address (for contact tracing) shall also be obtained.

Medication Adherence

All medication prescriptions of selected patients for the study will be monitored and documented. Patients’ medication accessibility and medication-taking adherence will be monitored via a brief mobile phone call and the administration of a brief medication-taking adherence questionnaire on every appointment. There

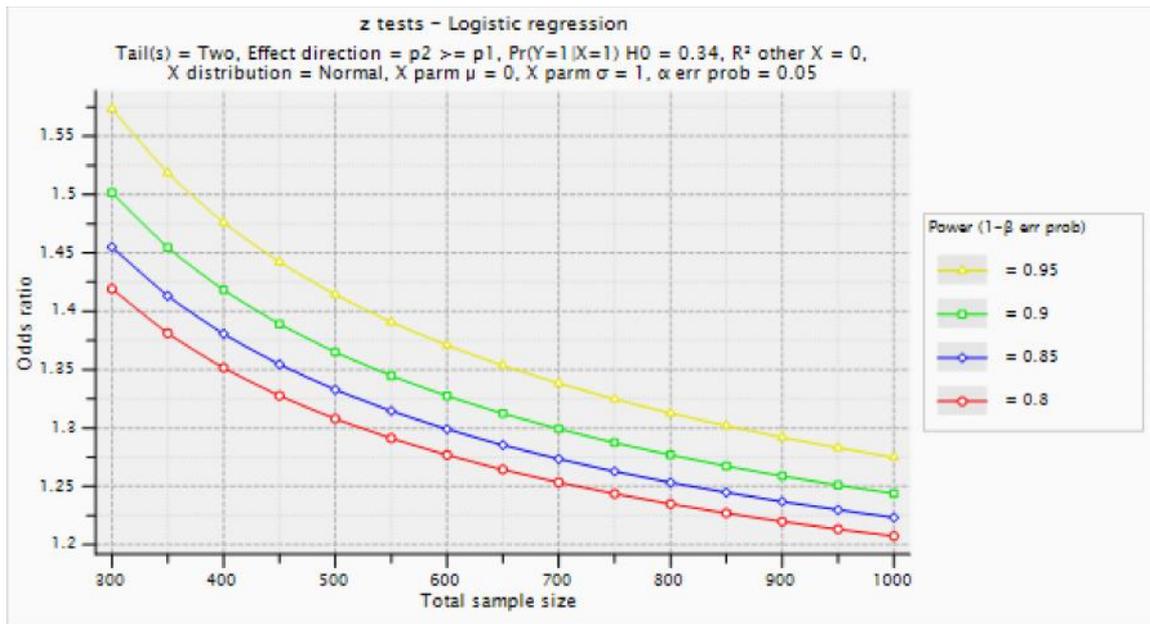


Figure 1: Shows the power calculation for the study.

will also be a short oral interview on medication accessibility and adherence of the patients with caregivers accompanying patients to their appointments. These steps will provide the study information on behaviours and barriers to medication accessibility and adherence of the patient.

Questions regarding medication adherence will be asked at baseline and during follow-up visits. This medication adherence questionnaire will ask questions on how often patients take their HF medicines, what factors/events may lead to their missing medicines, and reasons why they may miss medications.

Capture of Dietary Questionnaire

A dietary questionnaire shall be administered to the patients. This will be used to collect information about the type, portion size, quantity, and frequency of commonly consumed foods. This will incorporate validated nutritional information in Nigeria.

Economic cost analysis

The patient's access to different types of medical care over the last 12 months will be assessed, as well as the costs incurred due to the medical visit. Medication affordability will be captured by asking patients about insurance coverage, how they pay for their care, and if they have had difficulties paying. Patients will be asked if they have had to take time off work due to HF-related symptoms or hospitalizations, and if they have not taken their prescribed medication over the last 12 months because of the cost.

All patient perspective costs (i.e., out-of-pocket medical spending) associated with outpatient care: direct costs (clinic visits, laboratory investigations, medications, transportations, or in-patient care (if hospitalized-hospital care, medical consultations, nursing care, utility fees, accommodation, feeding, ward consumables, surgery and procedures) associated with HF management in Ibadan shall be computed. The human capital approach will be used to estimate the indirect costs borne by patients as a result of seeking healthcare for HF.^{12,13,32,33} Healthcare costs shall be estimated for one year in the Nigerian Naira and will be converted to US Dollar [US\$] at the prevailing exchange rate at the time of the study. Catastrophic healthcare spending (CHS) occurs when out-of-pocket payments is above a given percentage of households' total income/total expenditure. Three thresholds, 10%, 20% and 40% will be applied to ascertain the burden of catastrophic healthcare spending at the patients' household level.

Sample size calculation

Though this study is prospective in design, it is largely exploratory because most of the objectives are descriptive in nature. For a descriptive study, a sample size of 400 is sufficient to estimate the level of any outcome with 95% confidence. However, to make adequate allowance for study objectives that require comparisons, we plan to recruit at least 800 patients. The figure below shows different effect sizes [Odds Ratio] attainable at different levels of statistical power and sample sizes. At 80% power, sample sizes from 400 and above will be able to detect risks in excess of 35%. The figure shows that a sample size of 800 has

sufficient power to identify risk factors with an Odds Ratios greater than or equal to 1.20.

Data management and statistical analysis

All variables will be summarised using appropriate descriptive statistics. Means and proportions will be estimated with two-tailed 95% confidence intervals. Continuous variables shall be presented as means and standard deviations (SDs) or medians with their 25th and 75th percentiles when the distribution of the data does not follow a Gaussian distribution. Categorical variables shall be displayed as frequencies and proportions. Group comparison shall be done with the Student's t-test, and Chi-square statistics shall be used for comparison of categorical variables. Survival function estimates shall be performed using the Kaplan-Meier method, and the difference shall be tested using the log-rank test. The follow-up shall be censored at 6, 12, and 24 months, 3 years and five years.

Subjects who died within the periods shall be constituted the event of interest for the purpose of survival analysis while those still alive or lost to follow-up shall be treated as censored. Multivariate analyses shall be carried as where necessary. Where appropriate, results shall be expressed as odds ratio (OR) with their 95% Confidence Intervals (95% CI).

Ethical considerations

Ethical standard

The Ibadan Heart Failure project will be conducted in full compliance with the principles of the Declaration of Helsinki or with the laws and regulations of Nigeria.

The study will adhere to the basic principles of the International Conference on Harmonization-Good Clinical Practice (ICH GCP E6) or to local law if it affords greater protection to the participant. Recruitment of subjects will start after approval is obtained from the Institutional Review Committee. Participant safety will be carefully monitored in the study.

Institutional Ethics Review Committee

The protocol, informed consent forms, and recruitment materials have been approved by the Joint University of Ibadan and University College Hospital Ethics Review Committee.

Participants and data confidentiality

The confidentiality of all participant information will be protected in accordance with national and international data protection laws. The study team will ensure that participants' anonymity will be maintained and that their identities are protected from unauthorized parties. We will also maintain documents (i.e., participant signed ICF, medical records, etc.) in strict confidence.

Research use of stored human samples, specimens, or data

The confidentiality of all participant information will be protected. Any stored data or material will be used only for purposes defined in the applications for ethics approval. Samples designated for protocol-defined analysis will be provided with a code to ensure that investigators can associate results relevant to safety with the personal information of the participants. After analysis, the remaining samples shall be destroyed.

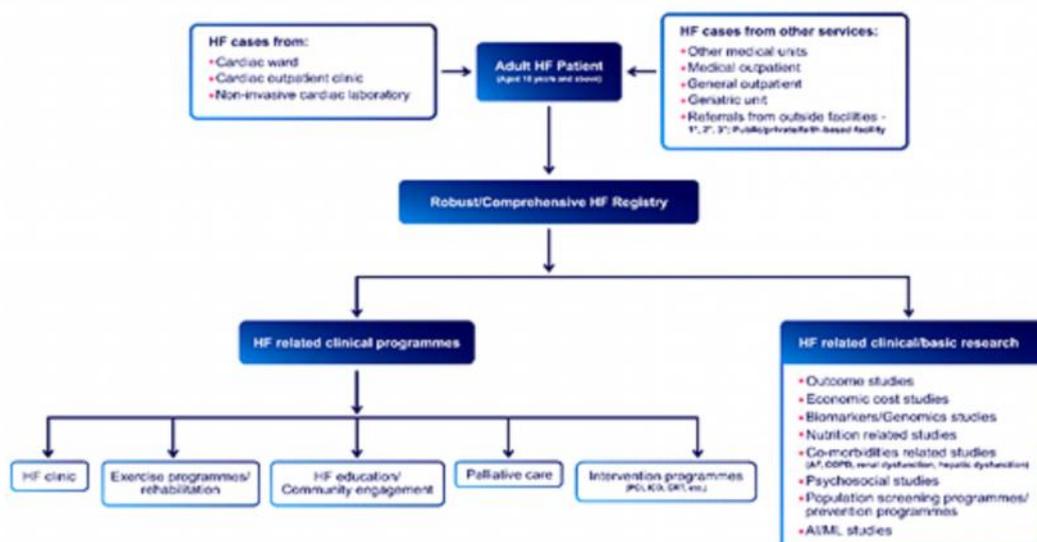


Figure 2 shows the flow chart for the study.

Discussion

The burden of HF is growing worldwide due to the ageing of the global population and better survival because of the availability of guideline-directed medical and device therapies. Comprehensive data on HF is lacking in Africa in general and in Nigeria in particular. Most of the available epidemiological information on the condition is based on robust research in high-income countries of North America and Western Europe.

The Ibadan HF project has been initiated to fill this gap. It is expected that the project will provide data on the contemporary aetiology and clinical profile and management of HF in Ibadan, which may be extrapolated to other parts of the country. It will also explore other areas of HF for which we currently do not have information, such as socio-demographics, intrahospital outcomes, short-, medium-, and long-term outcomes associated with the condition. It will also explore some social and economic factors associated with the disease. Finally, it will provide information on important debates as well as discussions on the prognosis of HF in Ibadan and Nigeria.

Study strengths and limitations

Because of the large cohort that will be recruited, this study is expected to provide real-life, pragmatic and useful information for care and management as well as for policy decisions.

Limitations

We acknowledge the inherent bias of hospital-based prospective cohort studies because unobserved variables may pose a confounding effect on the observed results.

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