In-hospital ventricular arrhythmia in heart failure patients: 7 year follow-up of the multi-centric HEARTS registry

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Abstract

Aims The aim of this study was to determine the incidence, predictors, and short-term and long-term outcomes associated with in-hospital sustained ventricular tachycardia (VT) and ventricular fibrillation (VF) collectively termed ventricular arrhythmia (VA) in the heart failure (HF) patients.

Methods and results The HEart function Assessment Registry Trial in Saudi Arabia (HEARTS registry) is a prospective national registry of patients with chronic HF from 18 tertiary care hospitals across Saudi Arabia. Diagnosis of HF was in accordance with American Heart Association/European Society of Cardiology definition criteria. The registry had enrolled 2610 HF patients during the 14 month recruitment period between October 2009 and December 2010. Occurrence of in-hospital cardiac events, prognosis, and outcome were monitored during the 7 year follow-up period. The incidence of in-hospital VA in HF was 4.2%. VA was more common among men, and mean age was lesser than non-VA patients (58.5 ± 16: 61.5 ± 15 years; P = 0.042). Smoking and family history of cardiomyopathy were significant risk factors of VA. Previous history of arrhythmia, ST elevated myocardial infarction, infections, and hypotension remained significant predictors of in-hospital VA associated with three to seven times more risk. Patients with VA had higher rates of in-hospital events like recurrent HF, haemodialysis, shock, sepsis, major bleeding, intra-aortic balloon pump, and stroke compared with those without VA, all being highly significant (P < 0.001). After adjustment for age, gender, and co-morbidities, in-hospital VA increased the risk of cardiogenic shock by 24 times, dialysis and major bleeding by 10 times, and recurrent congestive HF and pacing by five times. Survival analysis showed that all-cause mortality was significantly higher in the VA patients (P < 0.001). Presence of VA increased in-hospital and 1 month mortality to 23 and 17 times, respectively.

Conclusions Lower mean age of VA complicated HF patients is a matter of concern in the Saudi population. HF associated with VA increased in-hospital events and all-cause mortality indicating poor prognosis and survival. These findings enable risk stratification and reflect on the importance of early recognition of the clinical markers and predictors of VA prompting immediate management.

Keywords Heart failure; HEARTS registry; In-hospital ventricular arrhythmia; Saudi Arabia

Introduction

Heart failure (HF) is a serious and progressive cardiac illness that adversely affects quality of life, increases healthcare costs substantially, and is a major cause of mortality.¹⁻³ It affects about 26 million people worldwide,⁴ and the annual global cost burden was estimated at $108bn in 2012, which is projected to increase by 127% by 2030. The prevalence estimates are said to increase by 46% in the USA with characteristic dip in age at occurrence.⁵ The global public health burden of HF is enormous accounting for high rates of prevalence in European and Southeast Asian population.
HEARTS registry is a national prospective registry involving cardiac care hospitals across the Kingdom of Saudi Arabia, forming a representative sample of Saudi population. To stay brief, the Kingdom of Saudi Arabia is the largest country in the Arabian Peninsula, and it is the second largest producer of crude oil in the world with a gross domestic product per capita of 21,057.33 USD in 2017. The study design, details of study population, definition of study variables, and procedures have been well described and published previously. The registry had enrolled 2610 patients admitted into the coronary care unit/intensive care unit or the wards, with acute decompensated HF whether de novo (no previous history of HF) or with acute/chronic HF. Diagnosis of HF and the standard variables definitions were as per the American College of Cardiology, American Heart Association, and European Society of Cardiology definitions. HF patients with ejection fraction <30% and persistent New York Heart Association Class III or IV formed the study population. Development of sustained ventricular tachycardia or ventricular fibrillation or both while being hospitalized for HF management was the main outcome measure. VF was identified at admission or during the process of hospitalization if the patient showed irregular undulations of the electrocardiogram consistent with the diagnosis. VT was identified by a regular wide complex tachycardia lasting >30 s or requiring termination because of haemodynamic instability. Additionally, other in-hospital events and short-term and long-term all-cause mortality rates of the patients were also measured in the 7 year follow-up period. Patients less than 18 years of age, those who did not wish to participate, and those who were treated and discharged from the emergency department without hospital admission were excluded from the study. A verbal informed consent was obtained from the patients or their relatives. Ethical approval of the study was obtained by each of the hospital’s ethics committee or the institutional review board.

Statistical methods

The statistical analyses were performed using SPSS version 21.0 (SPSS Inc.). Continuous variables of normally distributed data were described using mean and standard deviation (SD), while median and inter-quartile range were used to represent skewed data. Test of significance was performed using the t-test or Mann–Whitney U test as needed to satisfy the normality of assumptions. Categorical variables were presented as frequencies and percentages, and bivariate associations between the two groups were compared using a z test for proportion. Predictors of mortality were assessed using both univariate and multivariate regression models to obtain independent predictors. Stepwise multiple regression models were applied to select independent predictors in the
Results

Patient characteristics

The HEARTS study obtained 4.2% incidence of in-hospital VA after 7 years of follow-up. Table 1 shows the comparison of the prevalence of risk factors among VA and non-VA complicated HF patients. In-hospital VA was significantly higher among men (P = 0.029), and the mean age was lesser compared with the non-VA group (P = 0.042). Other risk factors that appeared significant among the in-hospital VA patients were previous history of VF/VT (P < 0.001), family history of cardiomyopathy (P = 0.020), and smoking (P = 0.003). Although non-significant, VA patients were more likely to report history of non-ischaemic-related chronic HF followed by history of ischaemic heart disease. Hypertension and diabetes were the two most prevalent co-morbidities in both the groups.

Table 2 illustrates the differences in clinical presentation, investigations, and procedures between the two groups. Patients with VA had significantly higher heart rate and lower systolic blood pressure and diastolic blood pressure at the time of admission (P < 0.001). The most prevalent exacerbating factors for VA-related HF were history of arrhythmia (29%; P < 0.001), infections (28%, P = 0.04), ST elevated myocardial infarction (25.5%, P < 0.001), followed by uncontrolled hypertension (10.9%, P = 0.017). While ischaemic heart disease (60.9%-55.5%) was the most prevalent aetiology in both VA and non-VA HF patients; however, the differences were non-significant. Echocardiography and coronary angiogram showed higher left ventricular systolic dysfunction (P = 0.002) and higher prevalence of single and triple vessel disease compared with non-VA patients upon admission.
Table 3 presents the results of multivariate regression analysis with in-hospital VA as dependent variable and various co-morbid conditions, past cardiac events, and other exacerbating factors as independent variables. ST elevated myocardial infarction, arrhythmia, hypotension (systolic blood pressure < 90 mmHg), and infection at presentation remained significant as strong predictors in the final model showing independent association with VA.

Table 4 differences in in-hospital events and mortality between VA and non-VA patients.

Table 3 Multivariate regression analysis showing factors associated with in-hospital ventricular arrhythmia in heart failure patients

Table 4 Differences in in-hospital events and mortality between VA and non-VA patients

DBP, diastolic blood pressure; LV, left ventricular; proBNP, pro-brain natriuretic peptide; SBP, systolic blood pressure; SD, standard deviation; STEMI, ST elevated myocardial infarction; VA, ventricular arrhythmia.

Data are expressed in \( n \) (%). All-cause mortality includes cumulative of previous years.

CHF, chronic heart failure; CRT, cardiac resynchronization therapy; ICD, implantable cardioverter defibrillator; TIA, transient ischaemic attack; VA, ventricular arrhythmia.

Data are presented in \( n \) (%).

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haemodialysis, shock, sepsis, major bleeding, and intra-aortic balloon pump were highly significant among the patients with VA (P < 0.001). Survival analysis showed highly significant differences in all-cause mortality for in-hospital, 1 month, 1 year, and 3 years for VA patients compared with non-VA (P < 0.001).

The adjusted odds ratios of in-hospital events and mortality with respect to age and gender and in addition to presence of co-morbidities for VA are shown as differences in two groups in Table 5. Generally, presence of VA increased the odds of occurrence of adverse events and mortality. Cardiogenic shock when adjusted for co-morbidities showed the highest odds, escalating from around 20 to 24 times the risk. The estimated risk of developing other conditions like recurrent HF, haemodialysis, sepsis, major bleeding, and pacing increased manifold in presence of VA. Those with in-hospital VA had higher risk for in-hospital, 1 month, and 3 year mortality than those without VA.

**Discussion**

Development of ventricular arrhythmia in HF patients is a serious complication necessitating prompt intervention. Many studies have reported the magnitude and prognostic association with VA in patients hospitalized with HF. However, those studies were limited to PVCs and NSVT in HF and did not investigate sustained VT and VF due to high rate of mortality. To the best of our knowledge, this is the first study that expands the knowledge base to include the incidence, associated factors, and outcomes of patients with HF complicated by sustained VT and VF in Saudi Arabia.

| Variable          | Age-adjusted and gender-adjusted odds ratio | Age-adjusted, gender-adjusted, and co-morbidities-adjusted odds ratio |
|-------------------|--------------------------------------------|-------------------------------------------------|
| In-hospital events|                                            |                                                 |
| Recurrent CHF     | 3.9 (2.6–5.8)                               | 4.7 (3.0–7.2)                                  |
| Dialysis          | 7.2 (4.4–11.8)                              | 10.3 (5.8–18.4)                                |
| Shock             | 19.8 (13.1–30.0)                            | 23.7 (15.3–36.7)                               |
| Pacing            | 5.1 (2.1–12.5)                              | 5.8 (2.3–14.8)                                 |
| CRT               | 1.7 (0.7–4.3)                               | 1.7 (0.7–4.5)                                 |
| ICD               | 1.1 (0.5–2.4)                               | 1.2 (0.6–2.6)                                 |
| Major bleeding    | 9.6 (4.5–20.6)                              | 9.4 (4.3–20.7)                                |
| TIA/Stroke        | 2.9 (1.1–7.4)                               | 3.2 (1.2–8.6)                                 |
| Mortality         |                                            |                                                 |
| In-hospital       | 21.2 (13.8–32.6)                            | 22.8 (14.5–35.9)                               |
| 1 month           | 15.3 (10.1–23.3)                            | 16.7 (10.8–25.9)                               |
| 1 year            | 5.8 (3.9–8.7)                               | 6.6 (4.3–10.1)                                |
| 2 year            | 5.1 (3.4–7.6)                               | 5.8 (3.8–8.9)                                 |
| 3 year            | 4.9 (3.3–7.3)                               | 5.6 (3.7–8.5)                                 |

CHF, chronic heart failure; CRT, cardiac resynchronization therapy; ICD, implantable cardioverter defibrillator; TIA, transient ischaemic attack.

Data are presented as odds ratio (95% confidence interval).

The present study assessed the incidence, predictors, and mortality among HF patients with in-hospital VA using database from national HEARTS registry in Saudi Arabia. The cohort of HF patients showed 4.2% incidence of in-hospital VA. ST elevated myocardial infarction, previous history of arrhythmia, infection, and lower systolic blood pressure were independently associated with VA at the time of presentation. Other findings include strong association of VA with development of multiple in-hospital cardiac events and high rate of all-cause mortality. Some of the findings specific to Saudi population include lower age of occurrence and higher 1 month mortality.

The global incidence rates of in-hospital VA have been reported to be fairly consistent with our study. ATLAS study showed 5.5% and Worcester Heart Attack Study reported 4.7% incidence of in-hospital VA among myocardial infarction patients. On the other hand, there was a decline in out-of-hospital ventricular fibrillation/ventricular tachycardia in the population as in Finnish study, which showed 48% decrease from 1994 to 1999, and another study in Sweden had reported 18% reduction in incidence of VA after 17 years of follow-up. Clinical presentation at the time of admission of the VA complicated HF patients showed significant association with male gender, previous history of VT/VF, family history of cardiomyopathy, positive troponin, lower ejection fraction, higher heart rate at presentation, and triple vessel disease. HF registries from around the globe have identified older age and male gender as pivotal risk factors. To our surprise, the mean age was lower for VA complicated HF patients. Nevertheless, the mean age (61 years ± 15 SD) of the total cohort of HF patients in our registry was much lower in comparison with other registries from the American and European region (70–75 years ± 15 SD). These regional differences are controlled by many factors including economic status, literacy levels, genetic and lifestyle factors, and individual patient characteristics. However, this important finding reflects on implications like early mortality and multiple morbidity, thus necessitating urgent planning and implementation of framework of cardiac health intervention policies in Saudi Arabia. Other clinical risk factors were similar to reports from regional and global contemporary registries.

With regard to in-hospital course, adverse events during hospitalization were more frequent in the VA group, thereby exerting a direct influence on the prognosis and outcome. In addition, HF patients with VA showed significantly higher precipitating factors, which together augmented the risk of short-term and long-term mortality. The HEARTS registry showed higher rates of all-cause mortality than the global trials like EVEREST and ASCEND-HF. Other studies like GRACE, EFHS, and ATLAS are in accordance to our findings. Nonetheless, despite adverse outcomes associated with VA, the investigators of PROMISE study demonstrated that NSVT specifically in addition to other clinical parameters did not add more to the prediction of sudden death in moderate-to-severe HF patients, but early recognition and
management of in-hospital VA by prompt defibrillation improved survival outcomes.\textsuperscript{35} Herlitz and his colleagues and other studies demonstrated high rates of survival to hospital discharge upon < 3 min defibrillation after collapse among in-hospital VF patients.\textsuperscript{36–38} Hence, our findings suggest that the exacerbating factors may prompt vigilant monitoring of the parameters enhancing early recognition and facilitating swift initiation of defibrillation leading to substantial improvement in prognosis and better outcomes.

Furthermore, although standardized, the ICD and CRT therapy vary considerably between countries. The total prevalence of implant devices among HF patients in the present study was 12\% with similar use between VA and non-VA patients. Although this figure was overtly lower compared with countries like Italy, Israel, and Czech Republic with CRT penetration rate of 31–93\%, many other countries reported a prevalence range of 0–15\%.\textsuperscript{39} Data from the Gulf region involving seven countries also showed prevalence below 5\%.\textsuperscript{28} The reasons behind such regional disparities depend on several identified barriers like the type of healthcare centre, budget and finance, insufficient referrals, and lower physician awareness of guidelines. A detailed analysis of current cohort is however required to determine the cause of such low prevalence. Such underutilization may result in substandard healthcare delivery and management of HF patients raising concern. However, a larger study may be recommended involving referral hospitals and tertiary centres representative of the population to obtain unbiased results.

The study does contain certain limitations. First, the results of the study are based on data from a registry in which the enrolment of subjects is voluntary, which may impact the quality of data as being non-representative of the general population. Second, VA in our study included only patients with sustained VT and VF, which might have different prognostic implications in the setting of HF; information on other types such as PVCs and NSVT was not documented and hence beyond the scope of our study. Finally, the pre-hospital VA and/or sudden death were not captured in the registry, which might underestimate the incidence of VA in our population.

To summarize, smoking men aged above 55 years with previous history of arrhythmias or MI and with family history of cardiomyopathy are more likely to develop VA subsequent to HF. VA in HF was associated with higher risk of in-hospital events, adverse outcomes, and poor survival. The clinical implications of this research include risk identification based on presence of significant risk factors and predictors of VA that may potentially lead to early recognition and prompt management to improve outcomes. With regard to research implications, we suggest linking of more registries and develop risk stratification scores specific to Saudi population.

Conflict of interest
None declared.

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