

# Mortality Predictors in a Year after Implantation of Cardiac Defibrillators

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Received 2023-03-25; Accepted 2023-06-20; Online Published 2023-06-28

## Abstract

**Introduction:** Implantable cardiac defibrillators (ICDs) are commonly used to prevent sudden death in patients with heart failure. This study aims to determine patients' mortality rate and predictors in the first year after ICD implantation.

**Methods:** The study was a historical cohort based on patients who underwent ICD implantation at the Baqiyatallah Hospital from March 2009 to March 2018. ICD Implantation was used as secondary prevention for the patients.

**Results:** 777 ICD Implanted patients, including 27.5% females and 72.5% males with a mean age of  $64.2 \pm 0.8$   $63.5 \pm 12.7$  years, were included in the study. The mean one-year survival was  $11.29 \pm 0.1$  months. In multivariate analysis, age >75, hypertension, chronic obstructive pulmonary disease, chronic kidney disease, and hyponatremia were significantly correlated with shorter survival time.

**Conclusions:** Old age, chronic kidney or lung disease, hyponatremia, hypertension, and anemia are independent predictors of first-year survival in patients with an ICD implantation for heart failure.

**Keywords:** First-year mortality, Heart Failure, Implantable Cardiac Defibrillators.

## Introduction

ICD for the primary or secondary prevention of sudden cardiac death (SCD) in patients with heart failure has become one of the main components of treatment<sup>1-3</sup>. In addition, studies have confirmed the effectiveness of using ICD to reduce patient mortality from ventricular arrhythmias<sup>4-7</sup>.

However, treatment with ICD is less effective in some patients. For example, some studies show that patients with heart failure in the New York heart association class four have a higher mortality rate and are less likely to benefit from ICD implantation<sup>8, 9</sup>. Accordingly, some guidelines do not recommend ICD implantation for patients with a life expectancy of less than one year<sup>10</sup>. However, therefore, most of the existing guidelines currently consider the uncertainty of mortality factors in patients receiving ICD<sup>11</sup>.

Some studies focused on determining the factors associated with mortality in patients receiving ICD to reduce current uncertainty. Nevzorov et al. indicated

that age, atrial fibrillation, anemia, chronic renal failure, beta-blocker, and chronic lung disease are among the essential predictors<sup>12</sup>. Another study found an inverse relationship between a patient's body mass index and mortality after ICD implantation<sup>13</sup>. Besides, in other studies<sup>14</sup>, the NYHA criterion, hyponatremia<sup>15</sup>, age<sup>16</sup>, and history of coronary artery bypass graft surgery<sup>17</sup> have been reported as predictors of mortality in these patients.

This study aims to determine patients' mortality rate and predictors in the first year after ICD implantation.

## Methods

The study was a historical cohort based on patients who underwent ICD implantation in the Baqiyatallah hospital from March 2009 to March 2018. ICD Implantation was used as secondary prevention for the patients studied. The ICD was implanted according to the usual guidelines<sup>18</sup>. The patients with underlying

heart or other underlying diseases were excluded. The demographic, clinical, and comorbidity variables were included such as age, gender, Diabetes mellitus (DM), Hypertension (HTN), Dyslipidemia (DLP), Heart failure (HF), New York Heart Association (FC.NYHA), chronic kidney disease (CKD), ischemic heart disease (IHD), CABG, percutaneous coronary intervention (PCI), cerebrovascular accident (CVA), chronic obstructive pulmonary disease (COPD), Atrial fibrillation (AF), Ventricular tachycardia (VT), Ventricular fibrillation (VF), Bundle Branch Block, Anemia, ACE, ARB, Beta-blocker, Diur, Anti.Ar, Anti.Co, Smoke, Hyponatremia, Hyperkalemia, Left Ventricle ejection fraction, and type of ICD (single-chamber, dual-chambers, and three-chambers). Patients have followed up on their implantation at least one year after ICD implantation.

Kaplan-Mayer curve and Log-Rank statistics were used to assess survival and risk of mortality between ICD implantation types. Multivariate Cox regression was used to evaluate each clinical and comorbidity variable's independent prognostic values in predicting survival one year after ICD implantation. Each factor

was first entered into a univariate model; those found to be significant at a level of  $P < 0.20$  were entered into the multivariate model, and then variables with  $P < 0.05$  were reported. Data were entered and analyzed using SPSS-21. A significant level was considered 0.05.

## Results

Seven hundred seventy-seven patients included at least one year of follow-up after ICD implantation, 27.5% of females and 72.5% of males with a mean age of  $63.5 \pm 12.7$  years were ICD implantations.

Moreover, 10.7% of deaths occur during the first year of ICD implantation. Meantime for survival, ICD implantation within one year was  $11.29 \pm 0.1$  in durations 1-12 months (Table 1).

In the meantime, survival time in patients with single-chamber and dual-chamber ICD implantation ( $P = 0.015$ ) was higher than those who had three chambers ICD implantation ( $P = 0.012$ ) (Figure 1).

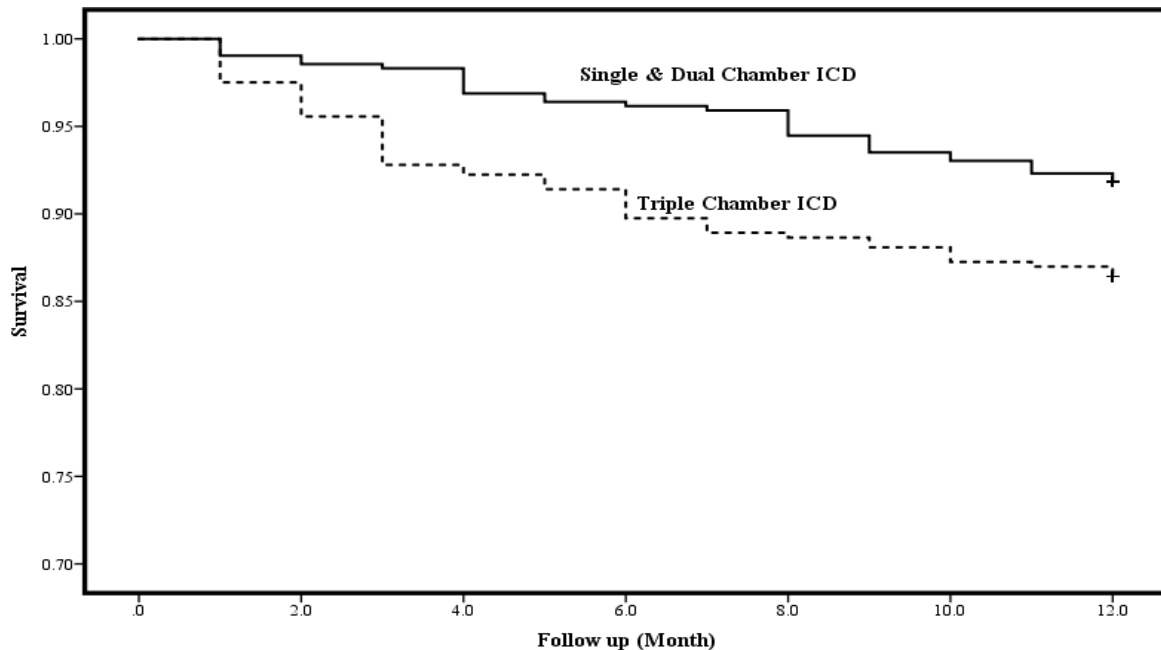


Figure 1: The Kaplan-Mayer curve and the Log-Rank test results show a significant difference between the two ICD groups ( $P = 0.012$ ).

Table 1: Summary of patient's demographic information.

		Single & Dual Chamber ICD (N = 416)	Triple Chamber ICD (N = 361)	P	Total (N = 777)
Age mean(SD)		62.58(13.72)	64.62 (11.33)	0.024 <sup>1</sup>	63.53 (12.70)
Gender N(%)	Female	101 (24.3)	113 (31.3)	0.029 <sup>2</sup>	214 (27.5)
	Male	315 (75.7)	248 (68.7)		563 (72.5)
Mortality N(%)	Lived	382 (91.8)	312 (86.4)	0.015 <sup>2</sup>	694 (89.3)
	Death	34 (8.2)	49 (13.6)		83 (10.7)
Survival (One Year)	Mean (S.E.)	11.5 (0.1)	11.0 (0.2)	0.012 <sup>3</sup>	11.29 (0.1)
	Median (S.E.)	12 (0.1)	12.0 (0.2)		12.0 (0.1)

1. Independent Sample T-Test, 2. Pearson Chi-Square Test, 3. Log Rank Test

Over 75 years old by 3.8 times, having HTN by two times, having HF by 2.9 times, having NYHA third class by 3.3 times, having NYHA fourth class by 6.4 times, the presence of CKD by 4.7 times, the presence of CABG by 1.8 times, the presence of COPD by 3.5 times, the presence of AF by 1.9 times, the presence of anemia by 2.6 times, the presence of Diur by 1.6 times, hyponatremia by 3.3 times, hyperkalemia by 2.5 times, and use of three Chamber ICD by 1.9 times increase mortality risk. Moreover, LEVF of less than 35% will increase mortality risk by 2.8 times (Table 2).

In single-chamber and dual-chambers ICD, age over 75 years by 4.2 times, HTN 2.76 times, FC. NYHA four class by 18 times, CKD 4.33 Equally, COPD by 3.54 times, anemia by 2.56 times, hyponatremia by 2.84 times, and hyperkalemia by 3.58 times significantly increase the risk of death. Moreover, in patients with three-chambers ICD implantation, age over 75 years old, history of heart failure, CKD, IHD, CABG, COPD, Anemia, LVEF < 35% and hyponatremia respectively 3.66, 4.99, 4.76, 2.29, 2.12, 3.27, 2.63, 7.89 and 3.93 times significantly increase the risk of death of patients (Table 3).

In multivariate analysis alerting, the older age group over 75 years has the presence of HTN, CKD, and FC. NHYA IV class and COPD significantly increase mortality risk (Table 4). Moreover, Multivariate analysis adjusting single-chamber, dual-chambers, and three-chamber ICD implantations associated with death, age over 75 years, and presence of HTN, CKD, and FC. NHYA four class, CKD, and COPD increase mortality risk significantly (Table 4).

The result of multivariate analysis indicated that the variables of heart failure (P = 0.048) and hyponatremia (P = 0.011) in the single-chamber and dual-chamber ICD implantation group and three-chamber ICD implantation group have a significant difference in the survival time of patients Figures 2.

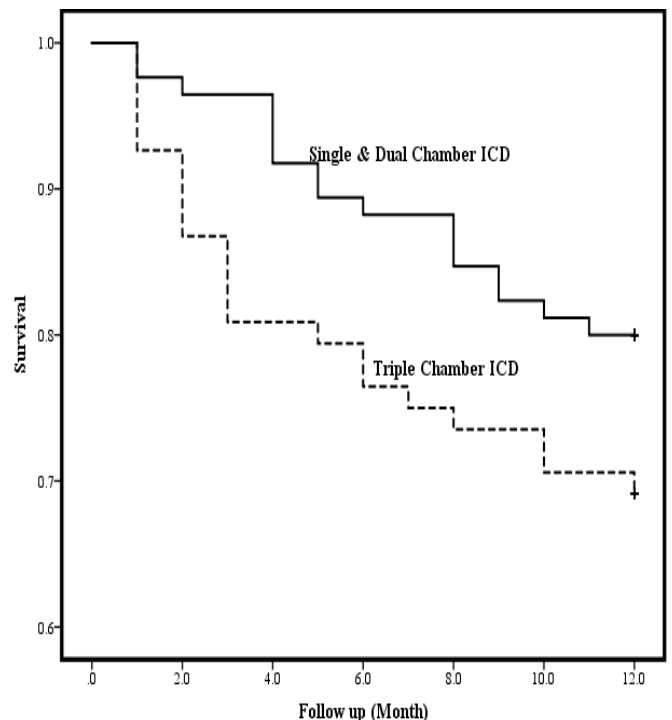


Figure 2: Kaplan-Meier curve in patients with Age >= 75. The log-Rank test shows no significant difference between the two groups (P = 0.094).

Table 2: The correlation between study variables and patient's mortality status

		Lived		Death		HR	95%CI		P <sup>1</sup>
		N	%	N	%		Lower	Upper	
Age	< 75	579	83.5	45	54.2	1.00			
	>=75	114	16.5	38	45.8	3.83	2.49	5.91	0.001
Gender	Female	192	27.7	22	26.5	1.00			
	Male	502	72.3	61	73.5	1.06	0.65	1.72	0.824
DM		260	37.5	38	45.8	1.37	0.89	2.11	0.157
HTN		345	49.7	57	68.7	2.09	1.31	3.32	0.002
DLP		197	28.4	27	32.5	1.19	0.75	1.89	0.451
HF		417	60.1	68	81.9	2.87	1.64	5.02	0.001
FC.NYHA	1	68	9.8	3	3.6	1.00			
	2	335	48.3	31	37.3	2.05	0.63	6.71	0.235
	3	264	38.0	40	48.2	3.31	1.10	10.69	0.045
	4	27	3.9	9	10.8	6.44	1.74	23.79	0.005
GFR<30		107	15.4	41	49.4	4.74	3.08	7.29	0.001
IHD		458	66.0	67	80.7	2.08	1.21	3.58	0.009
CABG		184	26.5	33	39.8	1.76	1.14	2.74	0.011
PCI		191	27.5	30	36.1	1.44	0.92	2.26	0.109
CVA		32	4.6	8	9.6	2.07	0.99	4.01	0.059
COPD		30	4.3	13	15.7	3.47	1.92	6.27	0.001
AF		111	16.0	22	26.5	1.85	1.13	3.01	0.014
VT		302	43.5	35	42.2	0.95	0.63	1.47	0.809
VF		47	6.8	6	7.2	1.09	0.47	2.51	0.837
bundle branch block		126	18.2	10	12.0	0.63	0.33	1.29	0.167
Anemia		216	31.1	46	55.4	2.59	1.68	3.99	0.001
ACE		74	10.7	7	8.4	0.79	0.36	1.73	0.551
ARB		417	60.1	55	66.3	1.28	0.81	2.01	0.291
Beta.B		444	64.0	46	55.4	0.72	0.47	1.11	0.128
Diur		402	57.9	58	69.9	1.64	1.03	2.62	0.039
Anti.Ar		304	43.8	38	45.8	1.08	0.71	1.67	0.717
Anti.Co		314	45.2	43	51.8	1.28	0.83	1.97	0.264
Smoke		250	36.0	29	34.9	0.95	0.61	1.48	0.804
ICD.Type	Single & Dual	382	55.0	34	41.0	1.00			
	Triple	312	45.0	49	59.0	1.73	1.12	2.68	0.014
LVEF	< 35%	512	73.8	74	89.2	2.81	1.41	5.62	0.003
hyponatremia	Na < 135	113	16.3	35	42.2	3.32	2.14	5.13	0.001
hyperkalemia	k >= 5	54	7.8	15	18.1	2.46	1.41	4.29	0.002

## 1. Univariate Cox Regression

Table 3: The correlation between study variables and patient mortality by ICD type.

		Single and Dual chamber ICD				Triple chamber ICD			
		HR	95% CI		P <sup>1</sup>	HR	95% CI		P <sup>1</sup>
			Lower	Upper			Lower	Upper	
Age	< 75	1.00				1.00			
	>= 75	4.24	2.16	8.30	0.001	3.66	2.08	6.45	0.001
Gender	Female	1.00				1.00			
	Male	0.87	0.41	1.87	0.724	1.30	0.69	2.45	0.420
DM		1.20	0.60	2.39	0.615	1.37	0.79	2.41	0.266
HTN		2.76	1.29	5.92	0.009	1.70	0.95	3.07	0.076
DLP		1.10	0.53	2.25	0.803	1.32	0.73	2.40	0.364
HF		1.87	0.92	3.77	0.082	4.99	1.55	16.04	0.007
FC.NYHA	1	1.00				1.00			
	2	3.33	0.44	25.44	0.247	1.13	0.26	4.89	0.867
	3	5.55	0.73	41.99	0.097	1.67	0.40	7.04	0.487
	4	18.01	2.10	55.42	0.008	2.08	0.38	11.38	0.396
CKD		4.33	2.20	8.53	0.001	4.76	2.71	8.34	0.001
IHD		1.85	0.81	4.24	0.148	2.29	1.11	4.72	0.025
CABG		1.30	0.64	2.68	0.469	2.12	1.21	3.72	0.009
PCI		1.41	0.71	2.79	0.328	1.70	0.94	3.10	0.080
CVA		2.54	0.89	7.21	0.080	1.78	0.64	4.95	0.269
COPD		3.54	1.37	9.15	0.009	3.27	1.53	6.97	0.002
AF		1.86	0.77	4.49	0.168	1.57	0.86	2.85	0.140
VT		0.80	0.40	1.58	0.519	1.14	0.65	2.01	0.643
VF		0.81	0.19	3.63	0.767	1.38	0.50	3.85	0.534
bundle branch block		1.56	0.69	3.62	0.283	0.23	0.07	0.73	0.013
Anemia		2.56	1.30	5.04	0.006	2.63	1.50	4.61	0.001
ACE		1.68	0.69	4.05	0.251	0.21	0.03	1.49	0.118
ARB		1.02	0.52	2.01	0.951	1.37	0.73	2.59	0.329
Beta.B		0.62	0.32	1.22	0.163	0.81	0.46	1.42	0.460
Diur		1.20	0.61	2.35	0.602	1.82	0.88	3.76	0.104
Anti.Ar		1.28	0.65	2.54	0.475	0.82	0.47	1.43	0.482
Anti.Co		1.29	0.66	2.52	0.463	1.29	0.74	2.26	0.369
Smoke		0.67	0.32	1.40	0.285	1.24	0.70	2.20	0.463
LVEF < 35%		1.74	0.79	3.85	0.169	7.89	1.10	57.15	0.041
hyponatremia		2.84	1.44	5.64	0.003	3.93	2.23	6.93	0.001
hyperkalemia		3.58	1.62	7.90	0.002	1.79	0.81	3.99	0.153

1. Univariate Cox Regression

Table 4: The correlation between the study variables and the patient mortality status.

		HR	95% CI		P <sup>1</sup>	
			Lower	Upper		
Total	Age>=75	2.91	1.84	4.60	0.001	
	HTN	1.74	1.10	2.79	0.021	
	HF	3.23	1.83	5.68	0.001	
	CKD	2.62	1.64	4.20	0.001	
	COPD	3.11	1.71	5.66	0.001	
	hyponatremia	2.10	1.32	3.34	0.002	
Single and Dual Chamber ICD	Age>=75	3.55	1.78	7.10	0.001	
	HTN	2.57	1.19	5.55	0.017	
	FC.NYHA (ref : 1)	2	2.60	0.34	20.10	0.360
		3	4.11	0.54	31.44	0.173
		4	12.39	1.44	66.45	0.022
	CKD	2.68	1.33	5.37	0.006	
COPD	3.00	1.14	7.82	0.026		
Triple Chamber ICD	Age>=75	2.65	1.48	4.74	0.001	
	HF	6.55	2.01	21.33	0.002	
	CKD	3.83	2.14	6.87	0.001	
	COPD	3.24	1.50	7.02	0.003	
	hyponatremia	2.59	1.45	4.62	0.001	
1. Multivariate Cox Regression (Forward LR method)						

## Discussion

The results showed that 10.7% of patients with ICD died during the first year after ICD implantation. The risk of death in the first year after ICD implantation has been reported in previous studies from 4.8% to 11%, indicating a wide range of patient mortality<sup>12, 19</sup>. Our study showed a similar mortality rate.

A previous study in Canada found that mortality was higher in elderly patients with congestive heart failure and diabetes<sup>20</sup>, consistent with our research results in the Iranian population.

In our study, those over 75 have a history of CKD, COPD, Hypertension, VT, and Beta. B, Left Ventricle ejection fraction and hyponatremia were significant independent mortality risk factors.

In addition, mortality and its related factors in patients with non-ischemic heart disease and ischemic heart disease with a history of ICD. History of AF and QRS more significant than 130 ms were independent predictors of mortality<sup>21</sup>. In the study of Nevzorov et al., in patients with ICD, independent factors of age over 75 years, history of AF, history of chronic lung disease, anemia, and decreased GFR levels were significant predictors of mortality in the first year<sup>12</sup>. In

our study, chronic kidney disease (defined as GFR<30) showed the highest hazard ratio (2.48) in predicting mortality among patients.

In another study of 1,703 patients, AF, DM, low body mass index (BMI), low mean arterial pressure, and low-grade NYHA were independent predictors of mortality in patients (22). Another investigation on 4,500 patients with ICD implanted as a primary prevention method showed that age over 75 years, heart failure (HF), a history of AF, chronic lung disease, chronic kidney disease, LVEF < 20%, and diabetes were independent risk factors of mortality<sup>23</sup>. Nevzorov et al. concluded that chronic kidney disease has the highest odds ratio in predicting mortality<sup>12</sup>.

Marini et al. observed more complications with increasing age at implantation and during follow-up. Also, they reported that higher NYHA class, creatinine level, and CHA2DS2-VASc score were identified as independent predictors of death, while age was not associated with a worse prognosis. Higher body mass index, NYHA class, and CHA2DS2-VASc score were also confirmed as independent predictors of hospitalizations or death due to any cause<sup>24</sup>. Demarchi et al. reported that age >80 years at the time of GR,

permanent atrial fibrillation (AF), advanced abnormal renal impairment (defined as glomerular filtration rate <30 mL/min), and a persistent indication of ICD at the time of GR were significant independent predictors of 1-year mortality at multivariable analysis<sup>25</sup>. In this study, we concluded that initially, the presence of age over 75 years, COPD, and chronic kidney disease has the highest risk ratio in predicting mortality. In another similar study, it was reported that there are three predictors of appropriate ICD interventions, including right ventricle dysfunction, age <40 years at ICD implantation, and a history of sustained ventricular tachycardia<sup>26</sup>. This study also showed that patients with three-chamber ICDs have a higher mortality risk ratio. COPD, age over 75 years, and CKD are the most influential variables in mortality. Patients with single-chamber and dual-chamber ICD types have almost the same risk and are at lower risk than those with three-chamber ICD types.

## Conclusions

Implantation mortality was determined after ICD in ischemic and non-ischemic heart failure patients. The results showed that age over 75, COPD, CKD, HTN, VT, Beta-blocker, and left ventricle ejection fraction variation could effectively predict mortality in primary prevention candidates with ICD.

## Acknowledgments

None.

## Conflict of Interest Disclosures

We declare there is no conflict of interest.

## Funding Sources

None.

## Authors' Contributions

Concept, Design, data analysis and preparing the manuscript: Morteza Khodaparast, Amir Hossein Maghari.

## Ethical considerations

Baqiyatallah's ethical committee confirmed the proposal of this study with IR.BMSU.REC.1397.112 cod.

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