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RESEARCH ARTICLE

Long Term Risk Of Device Related Complications After Implantable Cardioverter Defibrillator Implantation – a ten years cohort study

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Abstract: ***Background***: mplantable cardioverter defibrillators (ICDs) are widely used for primary and secondary prevention of sudden cardiac death in high-risk patients with ventricular arrhythmias and structural heart disease. Despite their life-saving role, ICD implantation may be associated with several early and late complications that can influence patient outcomes and healthcare burden.***Aim:*** To evaluate the long-term risk of device-related complications after ICD implantation and to determine the major predictors associated with these complications.***Patients and Methods:*** This retrospective cohort study was conducted at the Cardiology Department of Ibn Al-Baitar Cardiac Center between January 2010 and April 2019. A total of 923 patients who underwent de novo ICD implantation were included. Clinical records were retrospectively reviewed for demographic characteristics, indications for ICD implantation, echocardiographic findings, device type, and complications during follow-up. Statistical analysis was performed using SPSS version 23. Odds ratios and 95% confidence intervals were calculated, and p-values <0.05 were considered statistically significant.***Results:*** The mean age of the patients was 51.5 ± 17.2 years, with male predominance accounting for 677 (73.3%) patients. Secondary prevention represented the most common indication for ICD implantation in 741 (80.3%) patients. Single-chamber ICDs were used in 554 (60.0%) patients, while dual-chamber devices were implanted in 369 (40.0%) patients. The mean left ventricular ejection fraction was 28.6 ± 4.7%. The overall complication rate was 11.3%. Lead dislodgement was the most frequent complication occurring in 40 (4.3%) patients, followed by generator migration in 16 (1.7%), pocket hematoma in 15 (1.6%), infection in 12 (1.3%), lead fracture in 10 (1.08%), erosion in 9 (0.98%), and pneumothorax in 3 (0.33%) patients. Diabetes mellitus and re-intervention significantly increased the risk of infection. Female gender, ischemic cardiomyopathy, and dual-chamber ICD implantation were significant predictors of overall complications.***Conclusion:*** ICD implantation demonstrated acceptable long-term safety with no procedure-related mortality reported during the study period. Lead dislodgement was the most common complication. Female gender, dual-chamber ICDs, diabetes mellitus, and ischemic cardiomyopathy were important predictors of complications. Careful patient selection and close long-term follow-up may reduce complication rates and improve clinical outcomes.

Keywords: Implantable cardioverter defibrillator; Sudden cardiac death; Device complications; Lead dislodgement; Cardiomyopathy; Cardiac implantable electronic devices .

INTRODUCTION

Sudden cardiac death (SCD) remains one of the leading causes of cardiovascular mortality worldwide and is frequently associated with ventricular tachycardia (VT) and ventricular fibrillation (VF). Implantable cardioverter defibrillators (ICDs) have revolutionized the prevention of SCD through early detection and termination of life-threatening ventricular arrhythmias using anti-tachycardia pacing or electrical shock therapy. Since the first successful implantation of an automatic internal defibrillator in humans in 1980, ICDs have become an essential therapeutic modality for both primary and secondary prevention of sudden cardiac death.[1,2] Current international guidelines recommend ICD implantation for patients with prior ventricular arrhythmias, survivors of cardiac arrest, and selected patients with severe left ventricular systolic dysfunction who remain at high risk of fatal arrhythmias despite optimal medical therapy.[3–5] ICD therapy has been associated with significant reductions in mortality among patients with ischemic and non-ischemic cardiomyopathies.[6–8] Additionally, ICDs are beneficial in inherited arrhythmogenic conditions such as long QT syndrome, Brugada syndrome, hypertrophic cardiomyopathy, and arrhythmogenic right ventricular cardiomyopathy.[9–11] Modern ICD systems consist of pulse generators, sensing electrodes, and defibrillation leads that provide accurate arrhythmia recognition and effective electrical therapy. Technological advances have improved battery longevity, sensing capabilities, and device miniaturization, leading to broader clinical applications and improved patient survival.[12–14] However, despite these advances, ICD implantation is still associated with several acute and chronic complications that may adversely affect patient outcomes and quality of life. Complications related to ICD implantation include lead dislodgement, device infection, pocket hematoma, lead fracture, pneumothorax, device erosion, inappropriate shocks, and generator migration.[15–17] Some complications occur early after implantation, whereas others may develop years later. Lead-related complications remain among

the most frequent adverse events and may require re-intervention or lead extraction procedures.[18] Device infections are particularly serious because they are associated with increased morbidity, prolonged hospitalization, and higher mortality rates.[19,20] Several clinical and procedural factors have been reported to increase the risk of ICD-related complications. Female gender, diabetes mellitus, ischemic cardiomyopathy, renal impairment, dual-chamber devices, and re-intervention procedures are among the most commonly reported predictors.[21–24] Previous studies and registry data demonstrated considerable variation in complication rates depending on patient characteristics, operator experience, and duration of follow-up.[25–27] Although most complications can be managed successfully, they remain an important cause of healthcare burden and may negatively influence long-term outcomes. Large registries and observational studies have evaluated ICD-related complications in different populations; however, data from Middle Eastern countries and Iraq remain limited. Understanding the local pattern of complications and associated predictors is important for improving patient care and reducing adverse outcomes. Therefore, the present study aimed to assess the long-term risk of device-related complications after ICD implantation in a large cohort of Iraqi patients and to identify the major factors associated with increased complication risk.

Patients and Methods

This retrospective cohort study was conducted at the Department of Cardiology and Cardiac Electrophysiology Unit of Ibn Al-Baitar Cardiac Center. The study evaluated the long-term risk of device-related complications among patients who underwent implantable cardioverter defibrillator (ICD) implantation between January 2010 and April 2019. Data collection, review of medical records, and statistical analysis were performed between May 2019 and January 2020.

A total of 923 consecutive patients who underwent de novo ICD implantation during the study period were enrolled. Patients of both genders and different age groups were included. All implantation procedures were performed by experienced electrophysiologists and interventional cardiologists according to standard international recommendations and electrophysiology guidelines for cardiac implantable electronic devices.

The study included patients aged 18 years or older who underwent first-time ICD implantation for either primary or secondary prevention of sudden cardiac death. Patients with ischemic cardiomyopathy, non-ischemic cardiomyopathy, inherited arrhythmogenic syndromes, or documented ventricular arrhythmias requiring ICD therapy were eligible for inclusion. Only patients with complete clinical records and adequate follow-up information were included in the analysis. Patients who underwent generator replacement procedures, device upgrades from pacemakers to ICDs or CRT-D systems, or those with incomplete records were excluded from the study.

Baseline demographic and clinical data were obtained from patient records and included age, gender, smoking history, diabetes mellitus, hypertension, dyslipidemia, previous ischemic heart disease, history of ventricular tachycardia or ventricular fibrillation, prior cardiac arrest, and medication history. Clinical evaluation included a detailed physical examination and standard 12-lead electrocardiography for all patients before device implantation.

Transthoracic echocardiography was performed routinely before ICD implantation using commercially available echocardiographic systems. Left ventricular ejection fraction was assessed using the modified Simpson's biplane method whenever technically feasible. Additional echocardiographic evaluation included assessment of ventricular dimensions, regional wall motion abnormalities, valvular heart disease, and evidence of hypertrophic or dilated cardiomyopathy.

ICD implantation procedures were performed in a specialized cardiac catheterization and electrophysiology laboratory under complete sterile precautions. Local anesthesia with conscious sedation was used in all procedures. Venous access was obtained through the subclavian or axillary vein according to operator preference and patient anatomy. Single-chamber or dual-chamber ICD systems were implanted depending on clinical indication and physician decision.

Transvenous active fixation leads were positioned under fluoroscopic guidance. Right ventricular leads were commonly placed at the right ventricular apex or interventricular septum, while atrial leads in dual-chamber devices were positioned in the right atrial appendage. Electrical parameters including sensing thresholds, pacing thresholds, and lead impedance were assessed intraoperatively before fixation of the pulse generator within a prepectoral subcutaneous pocket. Defibrillation threshold testing was performed selectively according to patient condition and physician judgment.

Patients were followed regularly in the outpatient electrophysiology clinic after device implantation. Follow-up visits included clinical examination, device interrogation, assessment of lead integrity and device function, and evaluation of arrhythmic events or delivered therapies. Both early and late device-related complications were assessed during follow-up.
Early complications were defined as complications occurring within the first 30 days after implantation and included pocket hematoma, pneumothorax, acute lead dislodgement, device infection, and early generator migration. Late complications included chronic lead dislodgement, lead fracture, device erosion, late

infection, and generator migration occurring after 30 days from implantation.

Device infection was defined as localized pocket infection, device erosion, or systemic infection involving the ICD system requiring antibiotic therapy or device extraction. Lead dislodgement was defined as radiographic or electrical evidence of lead displacement requiring repositioning or re-intervention. Generator migration referred to displacement of the pulse generator from its original implantation pocket. Pneumothorax was confirmed radiologically after implantation procedures.
Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) software version 23. Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequencies and percentages. Independent Student's t-test was used for comparison of continuous variables, whereas Chi-square test or Fisher's exact test was used for categorical variables when appropriate. Multivariate logistic regression analysis was performed to identify independent predictors of ICD-related complications. Odds ratios with 95% confidence intervals were calculated, and p-values less than 0.05 were considered statistically significant.

The study protocol was approved by the Scientific and Ethical Committee of Ibn Al-Baitar Cardiac Center. The study was conducted according to the principles of the Declaration of Helsinki. Confidentiality and privacy of patient information were maintained throughout all stages of data collection and analysis..

RESULTS

The study showed that a total of 923 patients underwent ICD implantation during the study period. The mean age of the patients was 51.5 ± 17.2 years, with male predominance accounting for 677 (73.3%) patients, while females represented 246 (26.7%) patients. Most patients underwent ICD implantation for secondary prevention, accounting for 741 (80.3%) cases, whereas primary prevention represented 182 (19.7%) cases. Single-chamber ICDs were more frequently implanted than dual-chamber devices, accounting for 554 (60.0%) and 369 (40.0%) cases, respectively. The mean left ventricular ejection fraction was markedly reduced (28.6 ± 4.7%), and diabetes mellitus was identified in 387 (41.9%) patients.

Table 1: Baseline Characteristics of Patients

Variables	Value
Number of patients	923
Age (years), mean ± SD	51.5 ± 17.2
Female	246 (26.7%)
Male	677 (73.3%)
Primary prevention	182 (19.7%)
Secondary prevention	741 (80.3%)
Dual-chamber ICD	369 (40.0%)
Single-chamber ICD	554 (60.0%)
Ejection fraction (%)	28.6 ± 4.7
Diabetes mellitus	387 (41.9%)

study showed that the overall complication rate following ICD implantation was 105 (11.3%). Lead dislodgement represented the most common complication, occurring in 40 (4.3%) patients, followed by generator migration in 16 (1.7%) patients and pocket hematoma in 15 (1.6%) patients. Device infection occurred in 12 (1.3%) patients, while lead fracture and device erosion were identified in 10 (1.08%) and 9 (0.98%) patients, respectively. Pneumothorax represented the least common complication and was reported in only 3 (0.33%) cases.

Table 2: Overall ICD-Related Complications

Complications	Frequency (%)
Lead dislodgement	40 (4.3%)
Generator migration	16 (1.7%)
Pocket hematoma	15 (1.6%)
Infection	12 (1.3%)
Lead fracture	10 (1.08%)
Erosion	9 (0.98%)
Pneumothorax	3 (0.33%)
Overall complications	105 (11.3%)

The study showed that diabetes mellitus and re-intervention procedures were significant predictors of ICD infection. Diabetes mellitus increased the risk of infection by approximately 4.2 folds (OR = 4.2, 95% CI: 1.1–15.7, p = 0.031), while re-intervention procedures increased the risk by approximately 4.4 folds (OR = 4.4, 95% CI: 1.2–16.7, p = 0.029).

Table 3: Risk Factors for ICD Infection

Risk Factors	OR (95% CI)	p-value
Diabetes mellitus	4.2 (1.1–15.7)	0.031
Re-intervention	4.4 (1.2–16.7)	0.029

The study showed that ischemic cardiomyopathy represented the most common indication for ICD implantation, accounting for 427 (46.3%) patients, followed by idiopathic dilated cardiomyopathy in 325 (35.2%) patients. Hypertrophic obstructive cardiomyopathy was identified in 70 (7.6%) patients, while channelopathies and arrhythmogenic right ventricular cardiomyopathy accounted for 64 (6.9%) and 37 (4.0%) patients, respectively.

Table 4: Indications for ICD Implantation

Variables	Frequency (%)
Ischemic cardiomyopathy	427 (46.3%)
Idiopathic dilated cardiomyopathy	325 (35.2%)
HOCM	70 (7.6%)
Channelopathies	64 (6.9%)
ARVC	37 (4.0%)

The study showed that ischemic cardiomyopathy, female gender, and dual-chamber ICD implantation were significantly associated with increased risk of overall ICD-related complications. Patients with ischemic cardiomyopathy had approximately two-fold increased risk of complications (OR = 2.037, 95% CI: 1.472–2.818, p <0.001). Female gender was associated with 1.6-fold increased risk of complications (OR = 1.598, 95% CI: 1.082–2.360, p = 0.018), while dual-chamber ICD implantation increased the risk by approximately 1.5 folds (OR = 1.548, 95% CI: 1.104–2.170, p = 0.011).

Table 5: Predictors of ICD Complications

Risk Factor	OR (95% CI)	p-value
Ischemic cardiomyopathy	2.037 (1.472–2.818)	<0.001
Female gender	1.598 (1.082–2.360)	0.018
Dual-chamber ICD	1.548 (1.104–2.170)	0.011

The study showed that female patients were significantly associated with generator migration complications. Females represented 75.0% of patients with generator migration, whereas males represented only 25.0%. Logistic regression analysis demonstrated that female gender increased the risk of generator migration by approximately 8.6 folds (OR = 8.63, 95% CI: 2.76–27.01, p <0.001).

Table 6: Association Between Generator Migration and Gender

Gender	Generator Migration Positive	OR (95% CI)	p-value
Female	12 (75.0%)	8.63 (2.76–27.01)	<0.001
Male	4 (25.0%)	—	—

The study showed that most ICD-related complications occurred within the first year after device implantation, accounting for 61 (58.1%) complications. Early complications occurring within the first 30 days represented 34 (32.4%) cases. Late complications occurring after one year were observed in 44 (41.9%) patients. Lead dislodgement and pocket hematoma were more common during the early postoperative period, whereas lead fracture and device erosion were more frequently observed during long-term follow-up. A statistically significant association was observed between early postoperative period and lead-related complications (p = 0.014).

Table 7: Timing of ICD-Related Complications During Follow-Up

Timing of Complications	Frequency (%)	p-value
Within 30 days	34 (32.4%)	0.014
1–12 months	27 (25.7%)	0.021
>1 year	44 (41.9%)	0.038
Total complications	105 (100%)	—

The study showed that conservative medical treatment was sufficient in 39 (37.1%) patients with ICD-related complications, while surgical revision procedures were required in 48 (45.7%) patients. Lead repositioning represented the most common intervention and was performed in 31 (29.5%) patients. Device extraction due to severe infection or lead failure was required in 11 (10.5%) patients. No procedure-related mortality was reported during management of complications. A statistically significant association was observed between device infection and requirement for complete device extraction (p <0.001).

Table 8: Management Strategies for ICD-Related Complications

Management Strategy	Frequency (%)	p-value
Conservative treatment	39 (37.1%)	0.044
Lead repositioning	31 (29.5%)	0.018
Pocket revision	17 (16.2%)	0.032
Device extraction	11 (10.5%)	<0.001
Chest tube insertion for pneumothorax	3 (2.9%)	0.071
Total managed complications	105 (100%)	—

DISCUSSION

The present study evaluated the long-term complications associated with ICD implantation over a ten-year period in a large Iraqi cohort. The mean age of patients was 51.5 ± 17.2 years, with a clear predominance of males. Similar male predominance has been reported in previous studies evaluating ICD recipients.[1–3] The younger mean age observed in the current study compared with international registries may reflect demographic and epidemiological differences in the Iraqi population. Secondary prevention represented the major indication for ICD implantation, accounting for more than four-fifths of cases. This finding is consistent with earlier studies that demonstrated a high prevalence of ICD implantation in patients with prior ventricular arrhythmias and resuscitated sudden cardiac death.[4–6] The mean left ventricular ejection fraction in the present study was markedly reduced, which is comparable to findings reported in other cohorts involving patients with advanced cardiomyopathy and ventricular dysfunction.[7,8] The overall complication rate in the present study was 11.3%, which falls within the range reported in large registries and observational studies.[9–12] Lead dislodgement represented the most common complication, occurring in 4.3% of patients. Similar rates have been documented in previous studies evaluating ICD implantation outcomes.[13,14] Lead-related complications remain an important challenge because they often require re-intervention procedures and prolonged hospitalization. Device infection occurred in 1.3% of patients and was significantly associated with diabetes mellitus and re-intervention procedures. Previous studies and meta-analyses also demonstrated that diabetes mellitus is an independent predictor of device infection due to impaired immunity and delayed wound healing.[15–17] Re-intervention procedures may increase the risk of infection through repeated surgical manipulation and prolonged exposure of the device pocket.[18] In the present study, most infections were localized pocket infections, whereas a smaller proportion involved infective endocarditis. Female gender was significantly associated with increased complication rates and generator migration. Similar observations were reported in international registries where female patients experienced higher complication rates following ICD implantation.[19–21] Anatomical differences, smaller vascular size, and lower body mass may contribute to this increased risk among women. The present study also demonstrated that dual-chamber ICDs were associated with higher complication rates compared with single-chamber devices. This finding agrees with previous studies showing that dual-chamber devices involve more complex implantation procedures and additional leads, thereby increasing procedural risks.[22–24] Although dual-chamber devices provide additional diagnostic and pacing capabilities, their use should be carefully individualized according to patient characteristics and clinical indications. Ischemic cardiomyopathy was another major predictor of complications in the current cohort. Patients with ischemic heart disease often have more advanced structural myocardial damage and multiple comorbidities, which may increase procedural complexity and long-term complications.[25,26] Pneumothorax and device erosion were relatively uncommon complications in the present study and occurred at rates comparable to those reported in previous literature.[27–29] The low incidence of these complications may reflect increasing operator experience and improvements in implantation techniques over recent years. Importantly, no procedure-related mortality was documented during the study period. This finding indicates acceptable procedural safety and reflects the growing expertise in ICD implantation and management at specialized cardiac centers.[30].

CONCLUSION

ICD implantation demonstrated acceptable long-term safety with no procedure-related mortality reported during the ten-year follow-up period. Lead dislodgement was the most frequent complication, followed by generator migration and device infection. Female gender, diabetes mellitus, ischemic cardiomyopathy, and dual-chamber ICD implantation were significant predictors of complications. Careful patient selection, strict infection control measures, and regular follow-up are essential to minimize adverse outcomes.

Limitations

The study was retrospective in design and conducted at a single center, which may limit generalizability of the findings. Some clinical variables and long-term follow-up data were unavailable in certain patients. In addition, the study did not compare different ICD manufacturers or programming strategies.

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