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REVIEW ARTICLE

Implantable Cardioverter-Defibrillators in Patients with ESRD: Complications, Management, and Literature Review

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Abstract: ***Background*:** Cardiovascular diseases are the leading cause of death among dialysis patients, accounting for about 40% of all their mortalities. Sudden cardiac death (SCD) is culpable for 37.5% of all deaths among patients with end-stage renal disease (ESRD). Implantable cardioverter-defibrillators (ICDs) should be considered in dialysis patients for the primary or secondary prevention of SCD. Recent studies on the implementation of ICD/cardiac resynchronization therapy do not exclude patients with ESRD; however, individualized decisions should be made in this group of patients. A thorough evaluation of the benefits of ICD implementation in patients with ESRD requires several large-scale mortality studies to compare and follow up patients with ESRD with and without ICDs. In the present study, we sought to determine and clarify the complications associated with ICD implementation and management thereof in patients suffering from ESRD.

***Methods*:** To assess the complications allied to the implementation of ICDs and their management in patients with ESRD, we reviewed available related articles in the literature.

***Results and Conclusions*:** ICD implementation in dialysis patients has several complications, which has limited its usage. Based on our literature review, the complications of ICD implementation can be categorized as follows: (1) Related to implantation procedures, hematoma, and pneumothorax; (2) Related to the device/lead such as lead fracture and lead dislodgment; (3) Infection; and (4) Central vein thrombosis. Hence, the management of the complications of ICDs in this specific group of patients is of vital importance.

Keywords: Cardioverter-defibrillators, patients, ESRD, complications, management, literature review.

1. INTRODUCTION

In this review article, we discuss the complications of ICD implementation in patients with ESRD (if indicated) and also the management of these complications according to previous experiences. We conducted an exhaustive literature review; we initially selected 200 articles with related topics from the year 1978 and eventually selected 100 of them for a thorough perusal. Finally, we drew upon 56 articles to write this review. The acceptable complication rates in the general population justify guideline-based ICD implementation; however, in some ESRD patients, the risks may somehow outweigh the benefits.

2. CHRONIC KIDNEY DISEASE AND SUDDEN CARDIAC DEATH

Cardiovascular diseases are the leading cause of death among dialysis patients in that, they account for about 40% of all mortalities in this patient population [1, 2], with ventricular arrhythmias and sudden cardiac death (SCD) being the most prevalent causes [2]. There is currently a paucity of precise analysis of SCD-related factors in individuals undergoing dialysis. What is clear, however, is that electrolyte imbalance plays an important role in the outcome of patients on hemodialysis [3].

3. MORTALITY BENEFIT OF IMPLANTABLE CARDIOVERTER-DEFIBRILLATORS IN END-STAGE RENAL DISEASE

Implantable cardioverter-defibrillators (ICDs) should be considered as an option for the primary or secondary prevention of SCD, wherever indicated, whether among patients on dialysis or among those with normal renal functions. The guidelines of the American College of Cardiology/American Heart Association and the European Society of Cardiology recommend that dialysis patients who have survived SCD be treated with conventional methods, including ICD implementation, for secondary prevention [4]. Nonetheless, what is still underutilized for the treatment of patients with end-stage renal disease (ESRD) is the ICD. A retrospective study

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by Herzog *et al*. [5] on patients with ESRD showed that just 8% of the SCD survivors among their study population had undergone ICD implementation. In a large, contemporary, non-interventional study of community-based patients with heart failure and CKD, ICD placement was not significantly associated with improved survival but was associated with increased risk for subsequent hospitalization due to heart failure and all-cause hospitalization [6].

Large-scale prospective ICD cohorts/trials have excluded dialysis patients, and there is precious little information on the primary prevention of SCD in this group of patients.

Obviously, the survival benefit of ICDs is more considerable in non-dialysis patients than in dialysis patients [7]. Patients suffering from ESRD are admitted to hospitals for several other comorbidities and may die from other non-cardiovascular disorders. The majority of previous risk-benefit studies have focused on the indications and complications of ICD implementation in patients with chronic kidney disease (CKD) in comparison to those with normal kidney functions. A meticulous appraisal of the benefits of ICD implementation in patients with ESRD requires mortality studies seeking to compare ESRD patients with and without ICDs. Recent studies on the implementation of ICDs/cardiac resynchronization therapy have not excluded patients with ESRD; still, it is advisable that individualized decisions be made in this patient group [6-8]. In 2010, Hager *et al*. [9] showed better outcomes in their CKD patients treated with ICDs than in their CKD patients with conventional management. El Chami *et al*. in 2017 [10] showed ESRD patients are at significantly increased risk of mortality as compared with non-dialysis patients. While the majority of these patients survive more than one-year post-diagnosis, the three-year mortality is high (43%). Randomized studies addressing the benefits of ICDs in ESRD patients are needed to better define their value for primary prevention of SCD. Thus, the guideline-based usage of ICDs is recommended in patients suffering from CKD. The challenging issue here is the implementation of ICDs for primary or secondary prevention in stage 5 of kidney disease.

4. IMPLANTABLE CARDIOVERTER-DEFIBRILLATORS FOR PRIMARY PREVENTION

CKD is known to lessen the survival benefits of ICD implementation for primary prevention [11]. In a recent study in 2014, Pun *et al*. [12] performed a propensity-matched cohort study between ESRD patients with and without ICDs (for primary prevention) and reported no significant survival benefits for ICD usage in their study population.

The benefits of the primary prevention of SCD in ESRD patients may be attributed to age. Amin *et al*. [13] reported the survival benefits of ICD implantation in ESRD patients aged below 65 years. Hiremath *et al*. [14] in 2010 performed a small retrospective study, which compared ESRD patients with and without ICDs in terms of survival benefits. The authors focused on primary prevention indications and reported that ICD implementation was associated with a higher overall survival rate among their ESRD patients.

5. IMPLANTABLE CARDIOVERTER-DEFIBRILLATORS FOR SECONDARY PREVENTION

In 2005, Herzog *et al*. [5] conducted a retrospective cohort study on ESRD patients (460 with ICDs *vs*. 5582 without ICDs) based on Medicare Database and, in light of their results, supported the use of ICDs for secondary prevention after aborted SCD in dialysis patients. In a comparative study between ESRD patients with and without ICDs, Chen *et al*. [15] conducted a meta-analysis and showed increased overall survival benefits in their dialysis patients with ICDs. Another important issue is adequate medical treatment for heart failure with the use of such medications as beta-blockers, angiotensin-converting-enzyme inhibitors and angiotensin-receptor blockers in tandem with ICD implementation. Unfortunately, a factor liable to negatively affect survival among patients with ESRD is what is widely referred to as "therapeutic nihilism": these patients are likely to receive inadequate guideline-directed medical therapy because of several associated comorbidities such as ischemic cardiac disease, diabetes mellitus, and chronic heart failure [11]. This confounds the survival benefits of ICD implementation in this group of patients. Indeed, the advantages or disadvantages of ICD implementation in CKD/ESRD patients may be correlated with several factors such as increased age, ICD type, diabetes mellitus, and concomitant guideline-directed medical treatment [16].

6. COMPLICATIONS OF IMPLANTABLE CARDIOVERTER-DEFIBRILLATORS IN PATIENTS WITH END-STAGE RENAL DISEASE AND REPORTED APPROPRIATE MANAGEMENT

In 2009, Aggarwal *et al*. [17] compared the short-term consequences of ICD implementation in ESRD patients between those on dialysis and their non-dialysis counterparts in the National Cardiovascular Data Registry (NCDR) and found a fivefold increase in in-hospital mortality as well as a 20% increase in complications in the former group. Charytan *et al*. [18] examined 9528 hemodialysis patients with ICDs between 1994 and 2006 for both primary and secondary preventions and revealed very high rates of bacteremia (52%), device infection (4.2%), and death (45%) per year.

6.1. Implantation Site Hematoma

This complication in patients with ESRD is probably related to inappropriate venous access, coagulopathy, or platelet dysfunction because of uremic state [19]. In a study, the rate of bleeding complications associated with ICD implantation in the ESRD patients was about 7.5% [20]. In 2001, Pavias *et al*. [21] described pocket hematoma as a common complication and suggested electro-cautery as a useful way to reduce pocket-related bleeding. Withholding or reversing antiplatelet and anticoagulation medications in patients with low risk for thromboembolic events and applying absorbable collagen hemostats, thrombin patches, gelatin foams, and pressure dressings to incision sites to throw hemostasis forward can greatly reduce the risk of hematoma formation [22].

Table 1. Brief review of recent studies on the complications and management of ICD implementation in patients with ESRD.

Complication	Prevention/Management	Author	Journal and Year of Publication
Lead dislodgment	Pouch re-opening and lead reposition in early dislodgment New lead implementation after lead extraction in late dislodgment	Arijit Dasgupta *et al*. [28]	American Journal of Kidney Diseases (2007)
Implantation site hematoma	Withholding or reversing antiplatelet and anticoagulation medications in patients with low risk for thromboembolic events applying absorbable collagen hemostats, thrombin patches, gelatin foams, and pressure dressings to incision sites	Christine Tompkins *et al*. [20]	Cardiovascular Electrophysiology (2011)
Central vein stenosis	Left subclavian or cephalic vein approach Percutaneous balloon angioplasty Removal of CIED leads with stent insertion Stenting the SVC over the CIED leads	Theodore F. Saad *et al*. [29]	Seminars in Dialysis (2012)
CIED infections	Epicardial CIED leads re-establishment of the AV access and removal of the venous catheter. Wearable defibrillators Avoiding the combination of long-term venous hemodialysis catheters and CIEDs	Theodore F. Saad *et al*. [29]	Seminars in Dialysis (2012)
Central vein stenosis	Epicardial CIED leads Use of subcutaneous ICDs if possible	Arif Asif *et al*. [42]	Seminars in Dialysis (2012)
CIED infections	Subcutaneous ICDs Epicardial CIED leads No entrapment of a lead by a bare-metal stent or stent graft Percutaneous lead extraction Peritoneal dialysis	Arif Asif *et al*. [42]	Seminars in Dialysis (2012)
CIED infections	Complete lead displacement Medical therapy in bacteremia	Avirup Guha, *et al*. [40]	Heart Rhythm (2015)
Central vein stenosis	Subcutaneous ICDs PTA and stent placement	Rajiv K. Dhamija *et al*. [47]	American Journal of Kidney Diseases (2015)

ESRD, End-stage Renal Disease: CIED, Cardiac implantable electronic device; ICD, Implantable cardioverter-defibrillator; PTA, Percutaneous transluminal angioplasty.

6.2. Pneumothorax

This is not a common complication and is related to operator experience and also the difficulty of the subclavian puncture [21]. The incidence rate is approximately between 0.4% and 1.3% [23, 24]. In a study, kidney dysfunction was not associated with a higher occurrence rate of pneumothorax in the patients suffering from ESRD [25].

6.3. Lead Fracture

It is not a very frequent complication in ESRD patients. In a case report published in 2010, Sony Jacob *et al*. [26] described an ESRD patient with episodes of syncope despite having an ICD and reported that lead fracture was responsible for this ominous event. Additionally, they suggested a novel method to extract the lead *via* the right femoral vein. This method, however, needs more evaluation.

6.4. Lead Dislodgement

It is a change not only in the tip position of the lead, which is evident in chest X-ray but also in electrical lead parameters. In a study by Eberhardt *et al*., [27] the lead dislodgement rate was approximately 2.0%. In another study conducted in 2007, Arijit Dasgupta *et al*. [28] compared 41 ESRD patients with ICDs with 123 non-dialysis patients with ICDs and reported that in 88% of the cases, the ICDs were placed on the contralateral side of the dialysis access. The authors also reported that 3 lead dislodgments happened in their ESRD patients, while no such event occurred in their control group. Management differs based on several factors. Generally, in early dislodgment, pocket re-opening and lead reposition are possible and in late displacements, lead extraction and lead implementation in the chamber in which displacement has occurred are advised [28].

6.5. Venous Hypertension

Patients with hemodialysis catheters who have ipsilateral ICD leads are significantly prone to venous hypertension due to a high rate of venous blood return [29]. The mean blood flow in major fistulae ranges from 780 to 1204 mL/min [30, 31]. Venous hypertension owing to arteriovenous hemodialysis access and ipsilateral ICD leads has been described in many case reports [32, 33], with the ligation of the arte-

riovenous access deemed an effective way to control venous hypertension [34]. Moreover, flow reduction can be utilized to control this complication [35].

6.6. Infection

Being on dialysis has been shown to be an independent predictor of ICD infection [20], which may be because of frequent bloodstream access for hemodialysis and also dialysis catheters [36]. ICD infection in ESRD patients increases in-hospital mortality and the longevity of the hospital stay [37]. The only intervention proven in randomized clinical trials to decrease infection is prophylactic intravenous antibiotics [38]. The use of chronic suppressive antibiotics has been previously suggested [20]; be that as it may, the efficacy of this method of treatment should be tested with large randomized trials. The majority of ICD infection cases require whole-system removal alongside intravenous antibiotics [39].

In a study, lead extraction within 2 months of diagnosed ICD infection was reported to be associated with improvement in survival in the ESRD patients [40]. It is also worthy of note that in patients suffering from ESRD, transvenous lead extraction in the presence of endocarditis is also associated with morbidity and mortality [41]. Hence, primarily all physicians should focus on preventive measures before the occurrence of complications.

Epicardial leads are not exposed to the bloodstream and can be good alternative management [33], and subcutaneous and wearable defibrillators can reduce the risk of infection [42].

6.7. Central Vein Stenosis

ICD implementation ipsilateral to the dialysis catheter is associated with subclavian venous stenosis and thrombosis [43]. An injury to the vessel can lead to intimal hyperplasia and fibrosis [44]. These fibrous tissue bands may also contribute to the occlusive process. Unlike non-hemodialysis patients, ESRD patients are mostly symptomatic due to the high flow in the arteriovenous access [45]. The presence of hemodialysis can aggravate this stenosis. ESRD patients on hemodialysis whose arteriovenous fistulae in their upper extremity are ipsilateral to their ICD are at risk of symptoms related to venous stenosis such as edema of the face, neck, breast, shoulder, and arm [46].

Drew *et al*. [30] reported that central vein stenosis occurred in 21 of their 34 ESRD patients with cardiac rhythm devices. When central vein stenosis occurs, percutaneous balloon angioplasty and stent placement are the therapeutic options; still, the frequency of recurrence is noticeably high [47]. The expert consensus statements of the Heart Rhythm Society advise lead extraction before stent deployment [48]. Accordingly, in patients already on hemodialysis, contralateral lead placement is recommended. Using subcutaneous ICDs is an alternative with a view to preventing complications [47].

6.8. Peritoneal Dialysis

In a multicenter retrospective study in Italy, the incidence rate of SCD was not different between peritoneal dialysis and hemodialysis; however, the patients on hemodialysis had higher rates of comorbidities and mortality than those receiving peritoneal dialysis. Peritoneal dialysis is recommended in ESRD patients with no current AV access. In patients with venous catheters, wearable defibrillators and then peritoneal dialysis are recommended. If patients have transvenous ICDs and need an AV access, peripheral vein mapping is necessary to determine the risks and complications of another venous access [49].

7. ALTERNATIVE DEVICES

7.1. Wearable Defibrillators

Wearable ICDs have been shown to be effective for both secondary and primary preventions of SCD [50]. In a study, the event survival rate from these leads was 90 % in comparison with ICD therapy [51]. Wearable ICDs are indicated in cases in which the myocardial function may not permit the use of permanent devices such as uremia and uncontrolled volume overload [52]. Wearable ICDs are also indicated for use in previously infected devices in patients who are not paced dependent. Patients with ESRD are good candidates for wearable ICD therapy. The WED-HED trial, a multicenter cohort study, is an ongoing investigation to evaluate the impact of wearable ICD use on SCD in hemodialysis patients.

7.2. Subcutaneously Implantable Cardioverter-defibrillators

Subcutaneous ICDs do not transverse central veins and can minimize the risk of central vein stenosis and bacterial infections. In these devices, catheter and cardiac leads are placed in separate compartments instead of being placed in the bloodstream [18]. In a study on 79 patients with subcutaneous ICDs, the results showed that the subcutaneous ICDs did not increase the risk and complications in the dialysis and non-dialysis patients [53].

CONCLUSION

The total complication rate of ICDs has been reported to be significantly greater in patients with ESRD [15]. The rate of cardiovascular mortality remains high in these patients; nevertheless, more randomized clinical trials are required to further determine the risks and benefits [18]. Immune system dysfunction, uremic state, and coagulopathy are known to render patients with CKD/ESRD prone to greater device-related complications [54]. Decisions should be made on a case-by-case basis. The management of the complications of ICDs in this specific group of patients is vitally important. The 2 most common complications are ICD infection and central vein stenosis. In the case of infection, lead extraction should be considered. In addition, subcutaneous ICDs, wearable ICDs, and cardiac implantable electronic device lead greatly decrease the incidence of infection. For central vein stenosis, ICD lead removal and concomitant stent insertion, percutaneous balloon angioplasty, and subcutaneous ICD implementation are the recommended methods (Table **1**).

The acceptable complication rates in the general population justify guideline-based ICD implementation; however,

in some ESRD patients, the risks may somehow outweigh the benefits.

CONSENT FOR PUBLICATION

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CONFLICT OF INTEREST

The authors declare no conflict of interest, financial or otherwise.

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