

# Cardiovascular Implantable Electronic Device Leads in CKD and ESRD Patients: Review and Recommendations for Practice

# Theodore F. Saad,\* Dirk M. Hentschel,† Bruce Koplan,‡ Haimanot Wasse,§ Arif Asif,¶ Daniel V. Patel,\*\* Loay Salman,¶ Roger Carrillo†† and Jeff Hoggard,‡‡ ASDIN Clinical Practice Committee Workgroup

\*Department of Medicine, Section of Renal and Hypertensive Diseases, Christiana Care Health System, Newark, Delaware, †Interventional Nephrology, Renal Division, Department of Medicine, Brigham and Women's Hospital, Boston, Massachusetts, ‡Cardiac Arrhythmia Section, Brigham and Women's Hospital, Boston, Massachusetts, §Department of Medicine, Renal Division, Emory University School of Medicine, Atlanta, Georgia, ¶Department of Medicine, Division of Nephrology and Hypertension, University of Miami Miller School of Medicine, Miami, Florida, \*\*Volusia-Flagler Vascular Center, Daytona Beach, Florida, ††Division of Thoracic Surgery (Cardiothoracic Vascular Surgery), Department of Surgery, University of Miami Miller School of Medicine, Miami, Florida, and ‡‡Capital Nephrology Associates, Raleigh, North Carolina

# ABSTRACT

Cardiovascular implantable electronic devices (CIEDs) are frequently utilized for management of cardiac dysrhythmias in patients with chronic kidney disease or end-stage renal disease receiving hemodialysis. The survival benefit from use of implantable cardioverter defibrillators in patients with CKD or ESRD is not as clear as in the general population, particularly when used for primary prevention of sudden cardiac death. Transvenous CIED leads are associated with central vein stenosis resulting in significant adverse consequences for existing or future arteriovenous access. Venous hypertension from CIED lead-related central vein stenosis is a challenging clinical problem and may require repeated percutaneous interventions, replacement of the CIED, or creation of alternative arteriovenous access. Infections associated with transvenous CIED leads are more frequent and associated with worse outcomes in patients with renal disease. Epicardial CIED leads or other nontransvenous devices may reduce complications of both central venous stenosis and endovascular infection in these vulnerable patients. Consensus recommendations are offered for avoidance and management of complications arising from the use of CIEDs and arteriovenous hemodialysis access.

Pacemakers and implantable cardioverter-defibrillators (ICDs), collectively known as cardiovascular implantable electronic devices (CIEDs) are frequently utilized for treatment of cardiac rhythm disorders in patients with CKD and ESRD receiving hemodialysis. The ICD implantation rate in prevalent United States ESRD patients in 2008 was 0.7% (1). From 1996 to 2006, 9528 US Medicare-insured dialysis patients underwent ICD implantation, with 88% of these occurring after the year 2000 (2). The current prevalence of CIEDs in the ESRD population is not known. In a single-center study of 590 hemodialysis patients from 1995 to 2010

Address correspondence to: Theodore F. Saad, MD, 1092 Old Churchman's Road, Newark, DE 19713, Tel.: 302-472-9880; Fax: 302-472-9614, or e-mail: tsaad@delawarekidney.com Seminars in Dialvsis—2012

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(3), CIEDs were present in 43 patients (7.3%). Similar findings have been reported in a single-practice study of hemodialysis patients, showing a total CIED prevalence of 10.3% (ICDs 5.6% and pacemakers 4.7%) (4). It is not known if these data are representative of the dialysis population in general, but with nearly 400,000 patients receiving hemodialysis treatment in the US, it is clear that a significant number have CIEDs.

Cardiac dysrhythmias warranting pacemaker therapy commonly occur in patients with CKD or ESRD. Indications for pacemaker therapy in these patients are identical to the general population. The American College of Cardiology/American Heart Association guidelines for device-based therapy of cardiac rhythm abnormalities make no distinction for treatment of patients with CKD or ESRD (5).

Multiple clinical trials in the general population demonstrate a survival benefit from ICDs for both primary and secondary prevention of ventricular dysrhythmias (6–9). Given the high incidence of ischemic heart disease,

cardiomyopathy, and congestive heart failure in ESRD patients, many patients may meet criteria for ICD therapy. However, CKD and ESRD patients appear to derive lesser survival benefit from ICD treatment of ventricular tachycardia or fibrillation compared with patients with normal kidney function (2,10,11), probably due to the presence of multiple severe comorbidities that accompany late-stage CKD. It is therefore not surprising that the presence of CKD is highly predictive of early death in ICD recipients (12). Nevertheless, ICD's confer a significant survival benefit when comparing ESRD patients with and without an ICD for treatment of ventricular fibrillation and sudden cardiac death syndrome. One-, two-, and three-year unadjusted survival for dialysis patients receiving an ICD after cardiac arrest were 71%, 53%, and 36%, respectively, versus 49%, 33%, and 23% for dialysis patients who did not receive an ICD (13). Although overall mortality in this study of ESRD patients was higher than that reported for non-ESRD patients in the Anti-Arrhythmics versus Implantable Defibrillators (AVID) trial (9), the relative benefit from ICD therapy was similar (42% reduction in overall death risk for ESRD patients versus 38% reduction in the AVID trial). A recent meta-analysis of seven studies reporting on patients with ESRD having ICDs concluded that those receiving dialysis had a 2.7 times greater mortality compared with those not on dialysis (14). ESRD patients have longer hospital stays, higher in-hospital mortality (15), and higher rates of device related complications (2,16) following CIED implantation. Possibly as a result of poor outcomes reported for ESRD patients receiving ICD therapy, the number of ICD implantations in ESRD patients has leveled off from 2005 to 2008 (1). A recent review of ICD utilization in ESRD patients, recommended that the decision to implant an ICD should be based upon the health status, risk-benefit, and outcome expectations for the individual patient (17). There is a randomized controlled trial currently underway in Europe comparing outcomes in ESRD patients with or without ICD therapy for primary prevention of sudden cardiac death (18). Results of this trial have not yet been published.

# Central Venous Stenosis Associated with CIEDs

Central vein stenosis resulting from CIED leads has been well described in non-ESRD patients. Stenosis results from vessel injury leading to progressive intimal hyperplasia or fibrosis (19). This may occur at the vein puncture site or at any point along the vein wall which is in contact with a venous catheter or CIED leads through the superior vena cava. In patients with CIEDs, fibrous tissue bands extending from the vessel wall to the leads have been observed. These fibrous pedicles tether the leads to the vessel walls and may also contribute to the occlusive process (20–22). This process is particularly problematic in patients receiving hemodialysis using a tunneled venous catheter where the combination of a venous catheter and CIED leads may severely compromise the central vein lumen (Fig. 1).

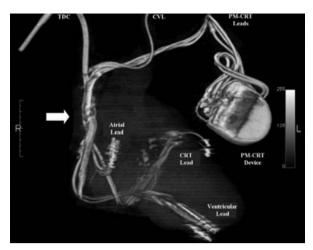


Fig. 1. CT recontruction showing superior vena cava (arrow) occupied by tunneled dialysis catheter (TDC), central venous line (CVL), and CIED (PM-CRT) leads.

Studies of non-ESRD patients demonstrate the development of central venous stenosis among patients with CIEDs. In a group of 229 patients, 64% developed central vein stenosis 6 months after placement of a transvenous pacemaker (23). However, only a small fraction of these patients (6/229, 2.6%) developed clinical signs of venous hypertension due to central vein stenosis. Among 100 patients with existing transvenous CIEDs, who underwent venography at the time of a subsequent device procedure (24), 26% demonstrated central vein stenosis, including 9% with complete venous occlusion; 74% had no central vein stenosis. All patients with stenosis or occlusion demonstrated well-developed collateral venous circulation, and none had symptomatic venous hypertension.

While CIED-associated central vein stenosis appears to have few adverse clinical consequences in non-ESRD patients, the scenario is very different for hemodialysis patients who have high-flow upper extremity arteriovenous access and ipsilateral transvenous CIED leads (Fig. 2). These patients are prone to developing clinically significant venous hypertension due to the high rate of venous blood return. The mean blood flow in mature fistulae ranges from 780 to 1204 ml/min (25,26) and in grafts 1109 ml/min (27). In some cases, vascular access flow rates exceed 2000 ml/minute (28). These high rates of venous flow may overwhelm the capacity of the compromised central veins and manifest clinically as edema of the upper extremity, face, neck, or breast, with or without associated dialysis access dysfunction (Fig. 3). In a series of 14 ESRD patients with a pacemaker ipsilateral to an arteriovenous dialysis access (29), 10 patients (71%) developed symptomatic venous hypertension and demonstrated subclavian vein stenosis or occlusion on angiography. Venous hypertension due to arteriovenous hemodialysis access and ipsilateral CIED leads has been described in numerous other case reports and series (30– 33). These studies report only small numbers of patients. However, given the expanding US hemodialysis population and CIED prevalence as high as 10% (3,4), a substantial number of patients are at risk for this

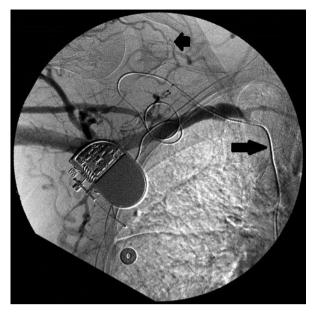


Fig. 2. Right subclavian and brachiocephalic vein occlusion associated with single CIED lead (long arrow). Extensive venous collaterals (short arrow) due to high-flow right-arm AV access.



Fig. 3. Right upper extremity swelling associated with right subclavian vein CIED leads and right-arm AV access.

complication. Compounding this risk is the preference of the left (nondominant) limb for placement of both the initial hemodialysis access and for CIED lead implantation. The left subclavian or cephalic vein approach is preferred by many implanting physicians for CIED lead insertion due to favorable venous anatomy and optimal shock vectors for ICD therapy.

The superior vena cava is the final venous pathway for all transvenous CIED leads and is susceptible to lead-induced injury resulting in symptomatic SVC stenosis and occlusion (34–38). Venous stenosis can occur at multiple sites and may be progressive to involve areas that were previously normal, including the SVC (39). Although studies estimate clinically significant CIEDattributed SVC stenosis to occur in up to 18% of ESRD patients (22), the true incidence of CIED-associated SVC stenosis is not known. In the setting of high-flow central venous return from an arteriovenous access, SVC obstruction may cause symptomatic venous hypertension regardless of the side of the CIED or arteriovenous access.

# Management of CIED-Associated Central Venous Stenosis in ESRD Patients with Arteriovenous Access

Percutaneous balloon angioplasty (PTA) without stent placement is the principal means of treating symptomatic central vein stenosis. Several studies report outcomes of PTA for treatment of central vein stenosis in the absence of CIED leads (40), with primary postintervention patency rates ranging from 12 to 50% at 12 months. Primary patency rates for central venous stenosis following PTA are poor in the presence of CIED leads, reported to be 18% and 9% at 6 and 12 months, respectively (22). Secondary patency rates, however, were more favorable at 95%, 86%, and 73% at 6, 12, and 24 months, respectively, requiring a mean of 2.1 interventions per year to maintain.

The impact of repeated PTA on the function of pacemaker or ICD leads is not well known. An in vitro study showed no significant effect on pacemaker lead structural integrity or function following exposure to multiple high-pressure balloons inflations (41). Similarly, repeated PTA of central vein CIED lead-associated stenosis in humans demonstrated no adverse effect upon CIED function based upon review of device interrogation records following PTA (42). However, concerns remain over long-term stability of lead function following multiple PTA. Furthermore, there is the possibility of enhancing lead adherence to the vein wall making future lead extraction more difficult.

PTA of the central veins is not always successful due to early elastic recoil or rapid redevelopment of stenosis post-PTA. In many patients, treatment of stenosis with PTA alone is very short-lived. For such patients without CIED leads, stenting of the central veins is often performed, although long-term outcomes have not been shown to be superior to PTA alone and repeated interventions are frequently required (40,43,44).

When PTA fails, stents have been employed in the management of symptomatic CIED lead-induced central venous stenosis. Various techniques have been described. One report described removal of the CIED leads, followed by angioplasty plus stent insertion, and then reinsertion of the transvenous CIED leads through the stented vein (45). Because the leads still traverse through the central veins and serve as a constant source of endothelial injury, there remains potential for restenosis within the stent or elsewhere in the central veins. In this context, repeated applications of this relatively complex procedure may not be practical. Another report described four nondialysis patients with symptomatic SVC stenosis associated with CIED leads, who were successfully treated by stenting the SVC over the CIED leads (46); no CIED device dysfunction occurred at 12 months and symptomatic relief was achieved in all the patients. A recent retrospective study reported the use of stents or stent-grafts over CIED leads in 14 hemodialysis patients with ipsilateral arteriovenous access and CIED-associated central vein stenosis who had failed conventional PTA (42). Primary patency rates at 6 and 12 months were 46% and 9%, respectively. However, more favorable 6 and 12 month secondary patency rates of 100% and 90% were achieved. A mean of 2.1 interventions per patient per year were required to maintain secondary patency. No patient in this study demonstrated any abnormality of CIED function. One patient developed staphylococcus aureus sepsis 44 months after central venous stent placement; this was successfully managed with antibiotic therapy not requiring stent or CIED removal. No patient in this study developed CIED lead infection or had other indications for device lead removal or exchange. However, it is evident that CIED lead entrapment by the stent would pose a significant impediment to the removal of infected leads, limiting the use of minimally invasive percutaneous lead extraction and necessitating a relatively complex open thoracotomy procedure with attendant increased risks and morbidity.

The Heart Rhythm Society expert consensus on transvenous lead extraction (47) recommends CIED lead removal prior to stent deployment at sites of lead-induced venous stenosis to avoid entrapment of the CIED leads. Complete device and lead removal is also recommended in the setting of sepsis or endocarditis. This report stipulates that "recommendations for lead extraction apply only to those patients in whom the benefits of lead removal outweigh the risks when assessed based on individualized patient factors and operator specific experience and outcomes." Problems associated with CIED lead-induced central venous stenosis in ESRD patients with arteriovenous access are not specifically addressed or referenced in this expert consensus.

The outcomes and risks of early-generation laser lead extraction have been published in two large multicenter studies (48,49). Successful lead extraction was achieved in 90% of cases. Complications occurred in 3% of cases, graded as severe in 1.9%, including cardiac tamponade, hemothorax, and pulmonary embolus. Death occurred in 0.8% of cases. Of note, there was a significant "learning curve" with more experienced operators achieving higher success and lower complication rates. The Lead Extraction in the Contemporary Setting (LExICon Study) is a retrospective, multicenter study of 1449 patients demonstrating improved results and outcomes using newer laser lead extraction techniques (50). Procedure success with complete lead removal was achieved in 96.5% of leads treated. Major adverse event directly related to the procedure occurred in 1.4% and mortality in 0.28% of patients treated. Overall all-cause hospital mortality was 1.86%, with significantly higher mortality reported in patients with endocarditis alone (4.3%), and endocarditis with elevated serum creatinine  $\geq 2.0 \text{ mg/dL}$ (12.4%). No data were reported for outcomes in patients with ESRD treated with dialysis. Thirteen centers participated in this study, representing low, medium, and high volume lead extraction programs. It should be emphasized that these results were achieved by expert practitioners at leading institutions in the United States and Canada.

Ligation of the arteriovenous access is an effective means to control symptomatic venous hypertension due to CIED lead-associated central vein stenosis or occlusion. In one series, 10 symptomatic patients underwent access ligation as initial management (29). Others have reported access ligation after PTA failure and subsequent venous catheter access or new arteriovenous access placement contralateral to the existing CIED (32,33). While effective in relieving symptoms of venous hypertension, this strategy results in the loss of a functional arteriovenous access and may preclude future accesses in the upper extremity ipsilateral to the CIED. For patients with significant SVC stenosis, construction of a new access contralateral to the CIED and ligation of the ipsilateral access would not be expected to improve symptomatic venous hypertension. Patients with CIED lead-associated central stenosis in whom PTA fails have also been treated with CIED lead removal, percutaneous management of the central vein lesions, and placement of epicardial leads (39).

Access flow reduction procedures are commonly performed for treatment of distal limb ischemia using surgical or minimally invasive techniques (51,52). Access flow reduction may also be utilized for treatment of complications associated with high-flow arteriovenous fistulae (53). Flow reduction would potentially improve venous hypertension associated with central vein stenosis, but has not been reported specifically for treatment of CIED-related venous hypertension.

# **CIED Lead Placement**

Transvenous routes for CIED lead insertion other than the subclavian or cephalic vein are seldom employed in common practice. The use of the internal jugular vein for CIED lead insertion has been reported in patients where other central venous access was not feasible (54). The internal jugular vein approach avoids direct injury to the subclavian vein; however, this does not spare the brachiocephalic vein or SVC, so the potential for central vein stenosis remains significant with any transvenous CIED leads. Furthermore, the jugular vein could be compromised, limiting its availability for future venous hemodialysis access. The femoral vein has been utilized for CIED lead insertion in patients with thoracic central vein occlusions and may provide an alternative to these veins for CKD and ESRD patients (55-59). However, this approach is rarely performed and risks damage to the femoral vein, iliac vein, and inferior vena cava with adverse impact upon future lower extremity arteriovenous access.

Epicardial CIED (pacemakers, implantable cardiac defibrillators and biventricular defibrillators) can be implanted surgically. By traversing through the subcutaneous tissue, epicardial leads avoid the central veins altogether and may be preferred over transvenous leads for some patients with CKD or ESRD (39). The risks of implantation of epicardial systems need to be considered and are likely highly dependent upon the experience of the surgeon. A 5-year experience from a single institution in pediatric patients (n = 60) demonstrated similar complication rates in children with endocardial (18%) versus epicardial (7%) pacing leads (60). A 2-year experience in a single center found no statistical difference in surgical mortality between thoracotomy ICD implantation (N = 92, 4.3%) and the transvenous group (N = 120, 3.3%), but increased surgical morbidity in the thoracotomy group (61). Most patients will require general anesthesia, but newer minimally invasive techniques, thoracoscopy, and robotic surgery has mitigated perioperative morbidity (62-67). Concerns have been raised regarding the effectiveness and survival of epicardial leads compared with endocardial leads. It was reported in the early 90s that conventional epicardial pacemaker leads had inferior 2-year lead survival  $(71 \pm 10\%)$  compared with endocardial leads  $(93 \pm 7\%)$  (68). However, more recent data obtained from children requiring a pacemaker have emphasized that epicardial leads have survival comparable with transvenous endocardial leads. (69). A recent study reported similar 2-year survival when comparing epicardial leads (91  $\pm$  5%) to endocardial leads (86  $\pm$  7%), and similar rates of lead failure, pacing, and sensing thresholds (70). A pediatric study comparing steroid-eluting large epicardial leads to endocardial leads reported 1-, 2-, and 5-year lead survival of 96%, 90%, and 74%, respectively. Epicardial and endocardial leads had similar survival, stability of acute and chronic sensing, and pacing thresholds (71). Additional adult and pediatric studies report no difference in lead recalls or fracture between when comparing endocardial with epicardial leads (60, 72, 73).

Epicardial ICD implantation via thoracotomy was the gold standard therapy for the treatment of ventricular arrhythmias in the early 1990s. Long-term follow-up of 67 patients shows no difference in the efficiency of defibrillating therapy between epicardial and transvenous systems for the treatment of both ventricular fibrillation and ventricular tachycardia (74). Many major clinical prevention trials for defibrillators in the 90s have included epicardial systems (75,76): AVID 5% (9); Cardiac Arrest Study Hamburg (CASH) 44% (77); Canadian implantable Defibrillator Study (CIDS) 10% (78); and Multicenter Automatic Defibrillator Implantation Trial (MADIT) 47% (6).

Epicardial implantation of Biventricular defibrillator (Cardiac Resynchronization Therapy for Heart Failure) has been well established (60,79,80). Long-term studies showed a similar event free survival compared with transvenous systems (81,82). A 2-year study in 12 patients with limited venous access in a single center showed that novel surgical approaches with the use of minimally invasive procedures can establish optimally functional pacing and ICD systems with low associated morbidities (83).

Recently, an entirely subcutaneous ICD has also gained attention. In nonrandomized studies, a subcutaneous ICD system successfully detected 100% of 137 ventricular fibrillation episodes induced during electrophysiological testing (84). The device also successfully detected and treated all 12 episodes of spontaneous, sustained ventricular tachyarrhythmia. While these preliminary results are encouraging, there is need for further study and optimal configuration of these devices. Future development of efficient electrode configurations that would maximize shock vector alignment and lower defibrillation threshold would be beneficial. Because of the problems associated with transvenous leads, the development of such a device is critically important and holds particular promise for use in hemodialysis patients (85).

#### **CIED** Infections in Hemodialysis Patients

Infection is an important consideration when planning for hemodialysis access or CIED implantation. and also for management of subsequent complications. Infection rates are significant in patients with arteriovenous access and are exceedingly high in patients dialyzing with central venous catheters (86). During 2008–2009 hospital admission rates for dialysis access-related infection and all-cause infection in ESRD patients were 114 and 471 episodes per 1000 patient-years, respectively (87). This rate is approximately 10 times higher than hospital admission rates of 35-50 for all-cause infection per 1000 population (88). The risk for bloodstream infection in ESRD patients dialyzing with central venous catheter access has been reported to be 7.6 times greater than that for patients using arteriovenous access (89).

In a population-based cohort study, the total CIED infection rate was 1.9 per 1000 device-years, with ICD infection rate of 8.9 per 1000 ICD device-years, and pacemaker infections occurring at a much lower rate, 1.0 per 1000 device-years (90). From 2004 to 2006, the national estimates of all CIED infections have increased by 57% (from 8273 to 12,979) (91). The annual rate of ICD infection was reported to be 1.53% in 2004, increasing to 2.4% in 2008, corresponding with increased percentage of ICD implantations as well as reported comorbidities (92). There are limited data regarding the incidence of CIED lead infections in ESRD patients compared with the general population. A recent study reported a high incidence of all-type infections in dialysis patients with ICDs, 988 episodes per 1000 patient-years in the first year after device implantation (2). The ICD infection rate was 42 per 1000 device-years, five times higher in hemodialysis patients than in the general population. Mortality of patients with CIED infection is high, increasing from 2.9% in 1993 to 4.7% in 2008; mortality was reported to be 4.3 times greater in patients with renal disease (93). Similarly, in-hospital mortality of CIED lead extraction for endocarditis was 4.3%, but increased to 12.4% when endocarditis was associated with elevated serum creatinine > 2.0 mg/dL (50). CIED leadassociated infection is of particular concern when a venous hemodialysis catheter is present; a remote source of bacteremia was found in 38% of late CIED infections, including 9% with a dialysis "Permacath" (93). The dangerous combination of transvenous CIED leads and a chronic venous dialysis catheter can be avoided by use of epicardial CIED leads (94) or establishment of AV access and removal of the venous catheter.

# Wearable Defibrillators

The wearable cardioverter defibrillator (WCD) (Life-Vest<sup>™</sup>; ZOLL Medical Corporation, Pittsburgh, PA) has been shown to be effective for both primary and secondary prevention of sudden cardiac death (95). Registry data collected on 3569 patients using WCDs from 2002 to 2006 showed that the device was generally well accepted, worn for >90% of the day in 52% of patients; successful cardioversion defibrillation occurred in 79/80 episodes of VT/VF and event survival was 90%, comparable with results of ICD therapy (96). WCDs are indicated for use in patients with cardiomyopathy, who do not yet meet criteria for permanent ICD therapy, such as during the early postmyocardial infarction period, or other circumstances where recovery of myocardial function may not warrant the use of a permanent device. This is particularly relevant to patients with uremia and uncontrolled volume overload new to dialysis therapy where significant improvement in cardiac function may occur after initiation of dialysis (97). WCDs are also indicated for use after explantation of previously infected transvenous device or other situations where unresolved infection precludes implantation of a permanent device. ESRD patients dialyzing with venous catheter access who are at highest risk for bacteremia may be good candidates for WCD therapy if they are felt to be at particularly high risk for sudden death (e.g., secondary prevention). After establishment of permanent AV access and removal of the venous catheter, a permanent ICD may then be implanted utilizing transvenous or epicardial leads as deemed appropriate.

# Summary

Prevention remains the most important strategy when addressing central venous stenosis in patients with CI-EDs and hemodialysis access. Use of CIEDs in CKD and ESRD patients should be judicious, carefully considering potential benefits of the device versus other risks, including adverse impact on existing or future arteriovenous access. Careful selection of veins for insertion of transvenous CIED leads and particular avoidance of the subclavian vein ipsilateral to existing or planned hemodialysis access will help to minimize central venous stenosis and reduce requirements for future interventions. Epicardial CIED leads entirely spare the central veins and may provide the optimal solution for patients with advanced CKD or ESRD. Patients with long-term venous hemodialysis catheters are at extraordinary risk for bloodstream infection and therefore intravascular CIED leads should be most strenuously avoided in these patients. In this setting, the use of epicardial or subcutaneous leads may reduce risk for serious infectious complications. Patients with CKD or ESRD receiving CIED therapy have very poor long-term survival; annual mortality is greater than 30%; and 5-year survival less than 20% (1,2). While the health care team must strive to improve these dismal outcomes, current decisions about vascular access and use of CIEDs must be informed by this unfortunate reality.

To provide optimal care for these highly vulnerable patients, it is essential to establish excellent cooperation and communication between all parties involved in their care including nephrologist, primary care physician, interventional physician, access surgeon, CIED implanting physician, and of course the patient. Vascular access coordinators may play a pivotal role in facilitating these important communications and coordinating care (98).

There is tremendous need for more and better quality studies of CIED-related issues in patients with CKD/ESRD treated with dialysis. These patients have been excluded from or underrepresented in most major prospective clinical trials of CIED therapy. Much of the knowledge we have about CIEDs in the CKD/ESRD population is based upon smaller series, case reports, and retrospective studies, all with inherent limitations. There are several particularly important areas for future study in CKD/ESRD patients, including: outcomes of ICD therapy for primary prevention of sudden cardiac death (18); outcomes and complications of modern transvenous lead extraction techniques; outcomes and complications of surgically implanted epicardial CIED leads; use of subcutaneous ICDs; and effect of repeated PTA on subsequent laser lead extraction outcomes.

# Recommendations for Management of Hemodialysis Vascular Access and Cardiac Rhythm Management Devices in Patients with Advanced Chronic Kidney Disease and End-Stage Renal Disease

- 1. All patients with advanced CKD and ESRD warrant preservation of peripheral and central veins that may be required for creation of arteriovenous access. These include patients with ESRD receiving hemodialysis as well as peritoneal dialysis therapy, and those with a functional kidney transplant who may require future hemodialysis due to transplant failure.
- 2. Prior to placement of a CIED in patients with Stage 4 or 5 CKD and ESRD, the cardiac device specialist, nephrologist, and primary care physician should carefully review the benefits and risks of CIED therapy particular with that patient, anticipated vascular access requirements, ESRD treatment modality, and overall prognosis.
- 3. In patients with Stage 4 or 5 CKD or ESRD who do not yet have arteriovenous access and require CIED therapy, a thorough venous assessment including venography or Doppler ultrasound vein mapping should be performed prior to placement of CIED leads. Transvenous CIED leads should be placed contralateral to the side of anticipated arteriovenous access (Fig. 4)

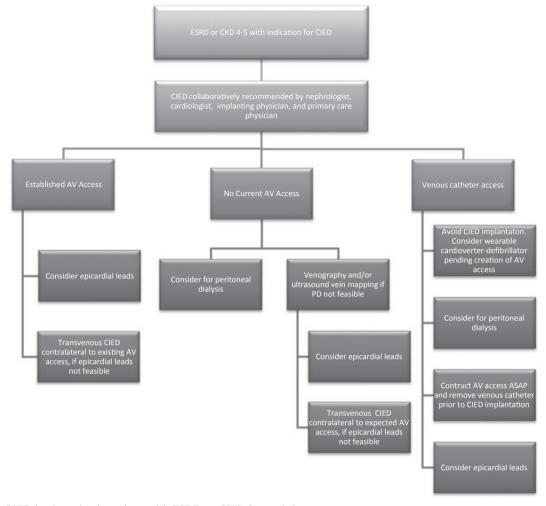


FIG. 4. CIED implantation in patients with ESRD or CKD Stages 4-5.

- 4. Patients with existing transvenous CIED leads who require hemodialysis access should undergo thorough venous assessment including central venography to evaluate the presence or absence of stenosis prior to creation of arteriovenous access; this will enable selection of the most appropriate limb and vessels for access construction. Whenever possible, new arteriovenous access should be constructed contralateral to the existing CIED (Fig. 5)
- 5. Epicardial leads should be considered in CKD and ESRD patients who require a new CIED or replacement of existing transvenous CIED leads. Programs without readily available local experts in epicardial lead implantation should work to develop this expertise, or identify regional referral centers where this procedure can be performed.
- 6. PTA without stent placement should be utilized as the preferred treatment of symptomatic central vein stenosis associated with transvenous CIED leads.
- 7. Entrapment of transvenous CIED leads by stent placement should be avoided. When stenting is deemed necessary, it is preferable to first extract

CIED leads and replace them via an alternative transvenous or epicardial route.

- 8. The combination of long-term venous hemodialysis catheters and CIEDs should be avoided due to the excessively high risk for bloodstream infection and central vein stenosis. A timeline and plan (including vessel mapping) for arteriovenous fistula creation should be pursued as urgently as possible in patients who require both a CIED and tunneled dialysis catheter. When clinically appropriate, for patients with transvenous CIED leads, delayed initiation of hemodialysis using permanent arteriovenous access may be preferred to earlier initiation of hemodialysis using a venous catheter.
- 9. Wearable cardioverter defibrillators should be considered for patients at risk for sudden cardiac death when the indication for a permanent implantable device has not been established, those with unresolved infection precluding use of an implantable device, and those with chronic venous catheter access pending creation of permanent AV access.
- 10. Peritoneal dialysis is an important form of renal replacement therapy. Preservation of central

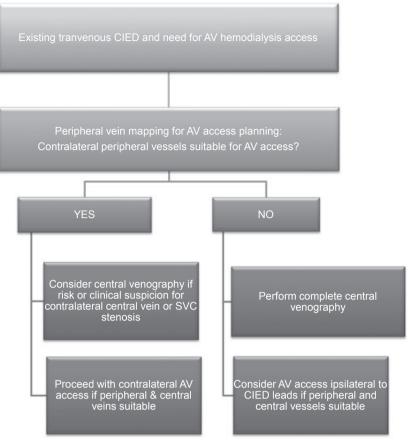


FIG. 5. Arteriovenous access construction in patients with existing CIED.

venous real estate remains critically important even in patients receiving peritoneal dialysis who may require an arteriovenous access in the future. Epicardial lead placement should also be considered in peritoneal dialysis patients who require CRMDs. Conversion to peritoneal dialysis should also be considered for suitable hemodialysis patients with arteriovenous access complications due to CIED lead-associated central vein stenosis.

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