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ORIGINAL ARTICLE

Central vein stenosis or occlusion associated with cardiac rhythm management device leads in hemodialysis patients with ipsilateral arteriovenous access: A retrospective study of treatment using stents or stent-grafts

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ABSTRACT

Purpose: **Symptomatic central vein stenosis commonly occurs when cardiac rhythm management device (CRMD) leads are placed via the subclavian vein ipsilateral to arteriovenous (AV) hemodialysis (HD) access. The purposes of this study were to determine the outcomes, complications, and patency following stenting of CRMD lead-associated central vein stenosis or occlusion, and to determine the effect of stents on CRMD function.**

Methods: **Fourteen HD patients with AV access and an ipsilateral CRMD were treated with stents for symptomatic central vein stenosis or occlusion following inadequate response to angioplasty from January 2005 to December 2009. Subsequent access interventions, complications, and outcomes were reviewed retrospectively. Cardiology records were examined to assess CRMD function.**

Results: **Treatment of stenosis or occlusion with angioplasty and stenting resulted in 100% procedural success and no complications. At 6 and 12 months, respectively, primary patency rates were 45.5% and 9.0%; primary-assisted patency rates were 90.9% and 80.0%; secondary patency rates were 100% and 90.0%. There were 42 repeat interventions performed in 12 patients; five received additional stents. The mean number of subsequent interventions was 3.2 per patient (2.1 per patient-year). All CRMD testing demonstrated normal function with no device or lead failure. Seven of the 14 subjects died resulting in a 35.3% annual mortality rate. No deaths were attributable to dysrhythmia or CRMD failure and no patient required CRMD removal or exchange.**

Conclusions: **Placement of stents for CRMD lead-associated stenosis or occlusion yields high success and low complication rates with no effect on CRMD function. Patency rates are similar to those reported in other series of central venous stents.**

Key words: Hemodialysis, Arteriovenous access, Central vein stenosis, Stent, Pacemaker, Implantable defibrillator cardioverter

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INTRODUCTION

Pacemakers and implantable cardioverter-defibrillators (ICDs), collectively known as cardiac rhythm management devices (CRMD), are frequently and increasingly utilized for treatment of cardiac rhythm disorders in patients with end-stage renal disease (ESRD) receiving hemodialysis (HD) (1). ESRD patients exhibit high rates of co-morbid cardiac conditions for which CRMD therapy may be warranted including ischemic heart disease, dysrhythmias, cardiomyopathy, and congestive heart failure. Significant survival benefit has been demonstrated from the use of ICDs in ESRD patients for treatment of ventricular fibrillation and sudden cardiac death syndrome (2), although a higher rate of device related complications has also been reported (3, 4). HD patients may not derive as great a benefit from ICD implantation as non-dialysis patients due to the exceedingly high mortality rate in HD patients with cardiac co-morbidity (5, 6).

Central venous stenosis occurs frequently in patients with CRMD leads. This may be due to injury at the vein puncture site or at other points along the vein wall in contact with the device lead. Central venous catheters demonstrate fibrosis or intimal hypertrophy in any segment of

the vein from the puncture site through the superior vena cava (7). One report demonstrated the presence of central vein stenosis by venography in 129/229 (64%) non-dialysis patients 6 months after placement of a transvenous pacemaker (8). However, only a small fraction, 6/229 (2.6%) developed clinical signs of venous hypertension due to central vein stenosis. Another study reported a series of 100 patients with transvenous CMRDs who underwent venography at the time of subsequent device procedures (9). Seventy-four percent of patients had no central vein stenosis, 17% had "partial venous obstruction" (>70%), and 9% had complete venous occlusion. All patients with stenosis or occlusion demonstrated well developed collateral venous circulation. No patient developed symptomatic venous hypertension. One large series over 10 yrs followed 6256 patients with permanent pacemakers and identified symptomatic venous hypertension in only 25 patients (0.4%) (10). These patients underwent venography with 22 demonstrating significant (>70%) venous stenosis involving the subclavian vein (n=9), superior vena cava (n=8), or both (n=5). Venous obstruction was complete in five patients. Central vein stenosis was identified at 7 months to 10 yrs (mean 26.2 months). Another study utilized intravenous contrast venography to evaluate central venous anatomy prior to pacemaker implantation in 150 patients (11). Baseline venous obstruction or anomalies were found in 10 patients (7%). At 6 months venography detected new stenosis in 19 patients (14%), all asymptomatic. A similar study utilized contrast venography to evaluate central vein stenosis in 105 consecutive patients presenting for ICD generator change (12). Venous obstruction was found in 25% of patients; this was classified as moderate (50-75%) in 10 patients (10%), severe (>75%) in six patients (6%), and complete occlusion in nine patients (9%). Previous pacemaker insertion resulted in a higher incidence of venous stenosis in this study (6/9, 67%), vs. those with no prior pacemaker (19/96, 20%). Another study utilized digital subtraction angiography to evaluate central veins before and after pacemaker insertion in 131 consecutive patients (13). Venous obstruction (narrowing >60%) was identified in 18/131 patients (13.7%) prior to pacemaker insertion. Follow-up venography was performed in 79 patients at a mean interval of 44 months. Venous obstruction was found in 26/79 patients (32.9%). No patients demonstrated any clinical symptoms or physical findings of venous hypertension. Venous thrombosis and stenosis associated with pacemakers and defibrillators was thoroughly reviewed by Rozmus et al (14).

In the setting of ipsilateral HD arteriovenous (AV) access, high blood flow may overwhelm the capacity of the compromised central veins, resulting in symptomatic and clinically significant venous hypertension manifesting as mild to severe limb swelling, with or without associated access dysfunction. This has been described in several case reports (15, 16, 35). One retrospective review demonstrated symptomatic venous hypertension in 10/14 (71%) HD patients due to subclavian vein occlusion or stenosis with transvenous pacemakers and ipsilateral AV access (17). In this report all patients were managed with the ligation of the AV access.

When central vein stenosis is diagnosed in HD patients with an ipsilateral AV access the principal treatment is percutaneous angioplasty. Using appropriately oversized balloons, 1-2 mm larger than the normal vein diameter, acceptable immediate results can usually be achieved (18, 19). In most patients, long-term patency can be maintained with repeated angioplasty (20). However, in some patients response to angioplasty is unacceptable due to immediate recoil, rapid restenosis, or vein rupture. Open surgical revision is rarely an option for the management of unsuccessful angioplasty in the central veins where intrathoracic surgery is technically challenging and associated with significant morbidity. Therefore, placement of a stent or stent-graft has been advocated for the treatment of central vein stenosis that cannot be adequately managed with angioplasty alone (18, 21, 22). Indications for venous stents as outlined by NKF-K/DOQI guidelines (23) include hemodynamically significant recoil post-angioplasty, rapid restenosis requiring re-intervention at less than 3-month intervals, or angioplasty-induced vessel rupture failing to respond to balloon tamponade. Complete vessel occlusion may also warrant stent or stent-graft placement, particularly in cases where the occlusion is difficult to cross and at high risk for re-occlusion.

The purposes of this retrospective study were to: 1) evaluate the procedural outcomes and patency of stents used for the treatment of central vein stenosis associated with CRMD leads; 2) assess CRMD function following stent placement; 3) identify complications related to the stent or CRMD leads.

MATERIALS AND METHODS

This was a retrospective study of ESRD patients cared for by a single nephrology practice with an integrated interventional program. The study protocol was approved by the Christiana Care Health System institutional review board. Informed consent for this study was obtained from all enrolled subjects or their next of kin.

Patient selection and demographics

HD patients with AV access and symptomatic central vein stenosis associated with ipsilateral CRMD leads treated with a stent or stent-graft from 1 January 2005 to 31 December 2009 were considered for inclusion in this study. The only exclusion criterion was unwillingness to provide

consent. Subjects were identified from a computerized HD vascular access database in which all diagnostic and interventional procedures related to HD access were continuously and prospectively recorded. All eligible patients were enrolled and formed the consecutive cohort for this retrospective study.

Patients were referred for evaluation and imaging based upon accepted criteria including: diminished access blood flow; access thrombosis; excessive needle site bleeding; abnormal physical examination of the access; difficulty with access cannulation; increased venous pressure; edema of the upper extremity, breast, head, or neck. All treatment decisions were made and interventions performed by the operating physicians as indicated according to their usual clinical practice. All subsequent access-related procedures and interventions were entered into the database. During the study period 6310 diagnostic and interventional procedures were performed on dysfunctional AV fistulae (AVF) or grafts; 374 stents or stent-grafts were placed representing 5.9% of all studies.

Sixteen stents were placed in 14 patients for treatment of central venous stenosis or occlusion associated with CRMD leads. Table I lists the subject and procedure details. Eight were male and six female with an average patient age of 72.6 yrs. Ten patients had an autogenous AVF and four a prosthetic graft. All were upper-arm accesses except for one forearm loop graft. In all patients the CRMD was implanted prior to creation of the AV access. The index-lesion involved the subclavian vein in 10 patients and the brachiocephalic vein in four patients. Twelve patients had AV access and CRMD on the left side and two on the right side. Thirteen of the 14 patients underwent at least one angioplasty procedure for the treatment of CRMD-related stenosis prior to the index stent procedure. Table I lists the indications for each stent placement. Stents were placed due to rapid restenosis (<3 months) following prior angioplasty or due to failed angioplasty at the time of the index procedure manifest by >30% residual stenosis post-angioplasty. Primary stenting was not performed. Several patients had more than one indication for stent placement. Venous occlusion was not a primary indication for stenting, but was considered a secondary indication in 12 patients. The mean interval from initial access placement to the index stent procedure was 23.8 months (range 0.8-51.9 months). The mean number of prior interventions for CRMD-related venous stenosis was 2.8 (range 0-6 procedures). The mean interval from the immediately preceding intervention for CRMD-related stenosis to the index stent procedure was 63 days (range 2-191 days). Only one patient was treated with a stent at the time of the first intervention.

TABLE I - PATIENT CHARACTERISTICS STENTS AND OUTCOMES

Subj. #	Age Yrs.	M/F	Access-Stent Interval; mos.	Access Type	R/L	CRMD			Prior Intervention		Stent Indication		Index Lesion			Stents		Additional interventions		
						Vein	Type	Indication	#	Interval Days	Primary	Secondary	%Pre-Stent	%Post-Stent	Length (mm)	Index	Stents Added	Interval	# at Site	# Total
1	69	F	39.1	Fistula	R	SCL	PPM	brady	6	191	Recoil	Occlusion	100	9	28	Fluency 10x60	0	180	4	4
2	72	M	14.1	Fistula	L	SCL	PPM	CHB syncope	4	11	Restenosis	Occlusion	100	22	38	SMART 14x60 Viabahn 13x50	0	263	2	2
3	72	F	9.4	Fistula	L	BCV	ICD	CHF, CM	3	43	Restenosis	Occlusion	100	n/a	n/a	SMART 14x60	0	n/a	0	0
5	81	M	51.9	Graft	L	BCV	PPM	CHB	5	2	Restenosis	Recoil	95	5	26	SMART 14x40	1	766	4	4
6	64	F	9.8	Graft	L	SCL	PPM	CHB	3	120	Recoil	Occlusion	100	23	23	Protégé 14x40	0	181	4	6
7	72	F	33.1	Graft	L	SCL	PPM	CHB	2	68	Restenosis	Recoil	67	0	29	Protégé 14x40	1	212	3	4
8	87	M	14.2	Fistula	L	SCL	PPM	CHB	1	71	Restenosis	Occlusion	100	26	86	Protégé 10x60 & 10x40	2	n/a	0	5
9	79	M	0.8	Fistula	L	BCV	ICD	CHF, CM	1	49	Recoil	Occlusion	100	9	42	Protégé 14x60	0	n/a	0	0
10	73	F	21.9	Graft	L	SCL	PPM	CHB	4	58	Restenosis	Occlusion	100	0	25	Protégé 14x40	3	112	6	7
11	73	M	47.4	Fistula	L	SCL	PPM	brady	4	83	Restenosis	Occlusion	100	24	18	Protégé 12x40	1	94	5	5
12	66	F	18.8	Fistula	L	SCL	ICD	CHF, CM	1	57	Restenosis	Occlusion	100	11	37	Protégé 12x40	0	333	1	1
13	51	M	14.2	Fistula	R	BCV	PPM	AF, AVN RFA	0	0	Recoil	Occlusion	100	21	35	Protégé 12x40	0	42	3	3
14	85	M	8.6	Fistula	L	SCL	ICD	CHF, CM	3	45	Restenosis	Occlusion	100	9	23	Protégé 12x60	0	n/a	0	0
15	71	M	49.5	Fistula	L	SCL	PPM	unknown	2	88	Restenosis	Occlusion	100	0	25	Protégé 12x40	0	238	1	1
Mean	72.6		23.8						2.8	63			97%	12%	33 mm				2.4	3.0
																			1.7 per yr	2.1 per yr

Abbreviations: BCV = Brachiocephalic Vein; SCL = Subclavian Vein; CHB = Complete Heart Block; PPM = Permanent Pacemaker; ICD = Implantable Cardioverter Defibrillator; CHF = Congestive Heart Failure; CM = Cardiomyopathy; Brady = Bradycardia

Technique

Procedures were performed in an office-based "access-center" or in a hospital angiography suite using strict aseptic technique and maximum sterile barrier precautions (24). The fistula or graft was accessed using an 18 gauge angiocatheter for initial diagnostic imaging and administration of medications. Complete digital subtraction angiographic imaging of the access circuit was performed using a 7 or 8 French vascular sheath and in some cases via selective central venous catheterization. Patients were administered midazolam and fentanyl as required to achieve adequate conscious sedation and analgesia. Heparin was not administered. Balloon angioplasty was the initial treatment for all patients. Balloon diameters were selected to provide one 1-2 mm over-dilation relative to the adjacent normal vein. Ultra-high pressure balloons (Conquest or Atlas, Bard PV, Tempe, AZ) were utilized as required to achieve complete balloon expansion. All radiographic images were reviewed retrospectively. Lesion length and percent stenosis pre-angioplasty and post-stenting were measured using digital imaging software (NeoLogica RemotEye, version 7.0.4, Cairo Montenotte, Italy) in accordance with published guidelines (25).

Lesions that failed to respond to angioplasty (>30% residual stenosis) or recurred within 3 months following previous angioplasty were considered for treatment with a stent or stent-graft according to NKF-K/DOQI guidelines (23). The use a "bare metal" stent or a stent-graft was determined by the operator based upon clinical and anatomic factors. Stents and stent-grafts used were all self-expanding nitinol devices inserted via an appropriately sized sheath, or in some cases using a "bare-back" technique. Stents included the SMART Stent (Cordis Corp, Warren, NJ) and Protégé (ev3 Endovascular Inc, Plymouth, MN). Stent-grafts included Fluency (Bard Peripheral Vascular, Tempe, AZ) and Viabahn (WL Gore, Flagstaff, AZ) tracheobronchial stent-grafts. The choice of stent or stent-graft was entirely operator dependent based upon the specific vessel and lesion characteristics. Post-deployment balloon dilation was not routinely performed for stents, but was performed for all stent-grafts. Procedural clinical success was determined by the operator post-procedure based upon substantial improvement in signs and symptoms of venous hypertension. No systematic or quantitative assessment of clinical success was performed in this retrospective study. Figures 1a, 1b, and 1c show typical features of CRMD central vein occlusion treated with angioplasty and stent-graft. Stents used in this study were approved for the treatment of biliary strictures or peripheral arterial disease; stent-grafts were approved for the treatment of tracheobronchial stenosis. All stents and stent-grafts were used "off-label" for the treatment of central venous stenosis.

No assessment of the CRMD function was performed

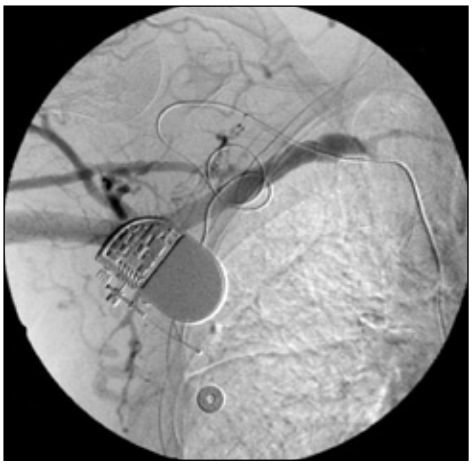

Fig. 1a - *Right upper extremity arteriovenous fistula with right subclavian and brachiocephalic vein occlusion associated with a pacemaker lead. Note extensive venous collaterals.*

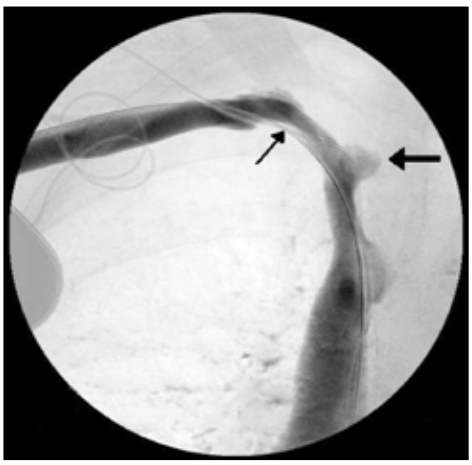

Fig. 1b - *Post-angioplasty image shows restored patency of the brachiocephalic vein with resolution of venous collaterals. There is moderate early recoil stenosis (light arrow) and a bulge arising from the medial aspect of the mid brachiocephalic vein (bold arrow) likely representing angioplasty induced venous pseudoaneurysm.*

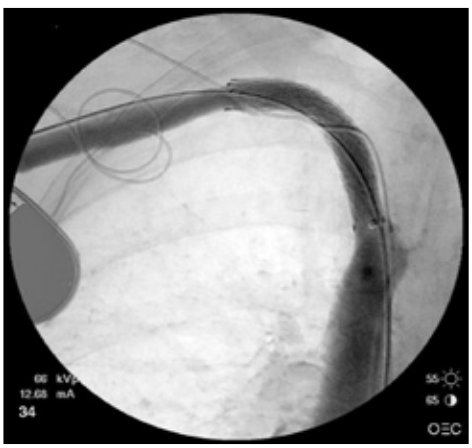

Fig. 1c - *A 10 mm x 60 mm stent-graft was placed extending from the right subclavian vein into the right brachiocephalic vein.*

before or immediately following stent placement. All procedures were performed with the patient on a cardiac monitor. Temporary pacemakers were not placed for these procedures. Post-intervention, patients were monitored for access function using the clinical and hemodynamic monitoring typically employed at their dialysis facility. Patients were referred for follow-up study based upon clinical criteria including signs and symptoms of recurrent venous hypertension. Angiography and additional interventions with angioplasty or stenting were performed as indicated.

Post-intervention access circuit primary patency, primary assisted patency, and secondary patency rates were determined using standard definitions (25, 26). The Kaplan-Meier method was used to calculate the cumulative probability of patency for each outcome measure. Frequency of repeat intervention was calculated as the number of interventions performed subsequent to the index procedure (stent or stent-graft insertion), divided by the time from the index study procedure to the termination of the study, death, or the abandonment of the access. Annual mortality was calculated by dividing the total number of deaths by the total number of patient years-at-risk.

CRMD testing was performed according to the usual device monitoring practice of each patient's cardiologist. No additional testing of the CMRD was performed in patients treated with stents or stent-grafts. CRMD function post-intervention was evaluated retrospectively by review of the patient's cardiology office records via telephone or direct record review. A device function questionnaire was utilized to inquire about: 1) failure to capture or sense appropriately; 2) change in impedance; 3) change in thresholds; 4) artifact detection or misinterpretation.

At the time of each clinical follow-up encounter, a complete clinical history was obtained, including hospitalizations, infections, and CRMD-related procedures. Hospital electronic medical records including admission history and physical notes, discharge summaries, consultations, operation reports, and all microbiology reports were retrospectively reviewed to identify any device-related infectious complications. For all deaths, the cause was determined by a history obtained from the patient's physician and family members and through review of the medical records.

RESULTS

Fourteen HD patients with symptomatic venous hypertension due to central vein stenosis or occlusion associated with a CRMD ipsilateral to a HD fistula or graft were treated with stents or stent-grafts. Mean pre-angioplasty stenosis was 97% with 12 patients demonstrating complete venous occlusion. Mean lesion length was 33 mm (range 18-86 mm). Procedural success was 100% with a mean residual stenosis of 12% (range 0-26%) following insertion of a stent or stent-graft. Clinical success was 100% with symptomatic improvement post-procedure. No major procedure-related complications were identified including CRMD malfunction, stent migration, vessel rupture, or infection.

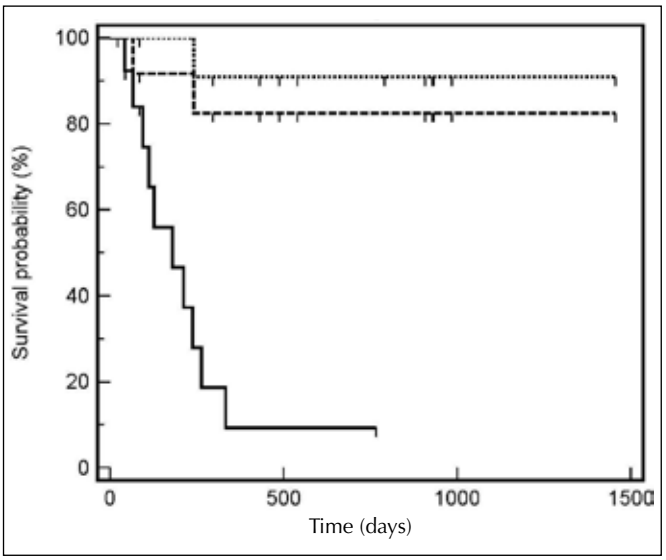

Fig. 2 - *Kaplan-Meier graph of post-intervention patency following initial stent or stent-graft placement for treatment of CRMD lead-associated central vein stenosis.*
Primary Patency: ——————
Primary Assisted Patency: – – – – – – – – – – –
Secondary Patency: .....

Primary patency of the access circuit following index stent or stent-graft procedure was 45.5% at 6 months and 9.0% at 12 months. Primary assisted patency was 90.9% at 6 months and 80.0% at 12 months. Secondary patency was 100% at 6 months and 90.0% at 12 months (Fig. 2). A total of 42 repeat interventions were required in the access circuit for all patients with a mean of 3.2 interventions per patient (range 0-7). The rate of all repeat interventions was 2.1 per patient-year. Thirty-three repeat interventions were performed at the original treatment area in 10 patients, including five who required additional stents placed at the target area. The mean number of subsequent interventions at the target lesion performed during the course of this study was 2.4 per patient (range 0-6). The rate of repeat interventions at the target lesion was 1.7 per patient-year.

Five episodes of access thrombosis occurred in two patients during the study, both with prosthetic grafts. All were successfully treated with percutaneous thrombectomy and angioplasty. One patient required fistula ligation due to arterial steal with severe digital ischemia.

No patient demonstrated any clinically evident abnormality of CRMD function during or following the stent procedure. All CRMD function and parameters determined

from cardiology office testing were normal. Medical record review disclosed no hospital admissions, consults, or interventions related to CRMD dysfunction.

There were no episodes of endocarditis or CRMD infection identified. No device or lead was removed or exchanged for any reason. One patient underwent placement of two additional stents for recurrent CRMD lead-associated central vein occlusion and recurrent cephalic arch stenosis 3.7 yrs after the index procedure. This intervention was complicated by post-procedure sepsis with methicillin sensitive *Staphylococcus aureus* requiring hospitalization and intravenous antibiotic therapy. After completion of a 4-week course of oxacillin, follow-up blood cultures remained negative and there were no direct sequelae of the infection. No other episodes of sepsis or suspected CRMD device infection were identified.

Seven of the 14 patients (50%) died during this study. Six of these withdrew from HD due to progressive debilitation and multiple medical complications. One patient developed respiratory failure and died after withdrawal of mechanical ventilation. Annual mortality in the study cohort was 35.3%. No patient death was attributed to CRMD dysfunction.

DISCUSSION

This study demonstrates that stents or stent-grafts are feasible for treatment of central vein stenosis or occlusion associated with CRMD leads and ipsilateral HD with no immediate or long-term adverse effects on CRMD function. All CRMD testing was normal following stent placement indicating no adverse effect of stents on the device function or lead integrity. None of the 15 patients reported in this series had any subsequent indication for device lead extraction or exchange. No published reports were found describing adverse effects of stent placement on CRMD function. Theoretically the stent could induce damage to the device leads or insulation leading to electromechanical disturbance of the CRMD or grounding through the conductive stent material. CRMD leads are manufactured with a very robust multi-layered coating which is quite resistant to external mechanical damage. In the venous system device leads are rapidly encased by a fibrous sheath potentially offering an additional protective barrier against injury from an adjacent stent (27).

Primary and secondary patency rates in this study are comparable to other reports of central venous stenting. There is little data to demonstrate the benefit of stents for central vein stenosis in HD patients (21). An uncontrolled study using the SMART™ stent (Cordis, Warren, NJ) reported mean patency of 14.9 months for stents used to treat central vein stenosis (28). Others have reported 6-month primary patency for stents used to treat central vein stenosis between 42% (29) and 74% (30). One uncontrolled study demonstrated no outcome benefit from the use of primary stenting vs. PTA alone for the treatment of central vein stenosis (30). There is no published data on the use of stent-grafts for the treatment of central vein stenosis or occlusion. In our cohort there was a very high rate of venous occlusion which may behave differently than non-occlusive stenosis. Primary patency and secondary patency in our study are comparable to other reports showing preserved long-term patency with re-interventions as indicated. It is difficult to make direct comparisons due to the relatively small patient numbers and differences in reporting methods and rates of venous occlusion.

A recent study reported results of angioplasty used to treat CRMD-associated central vein stenosis (20). Twenty-eight patients were treated with primary patencies of 18% and 9% at 6 and 12 months, respectively. Secondary patencies were 95%, 86%, and 73% at 6, 12, and 24 months, respectively, requiring 2.1 procedures per year to maintain. This study did not report how many patients had central vein occlusion.

There have been few published reports describing the use of stents for the treatment of central vein stenosis associated with CRMD leads. One study reported the use of angioplasty and stenting for the treatment of four patients with symptomatic superior vena cava (SVC) stenosis associated with pacemaker leads (31). In this report, stents were placed adjacent to pacemaker leads, entrapping them against the SVC wall. Sustained symptomatic improvement was achieved in all patients. Due to concerns about possible effects on pacemaker function, temporary pacemakers were placed in these patients prior to the stenting procedure. No patients demonstrated any abnormality of pacemaker function during stent insertion or at follow-up over 4-34 (mean 18.6) months. Another study reported three patients with SVC-syndrome due to CRMD lead-associated stenosis who underwent laser lead extraction prior to angioplasty and stenting. Two of the three patients had new CRMD leads inserted through the stented vessel. All had sustained symptomatic improvement over 24-month mean follow-up (32). There is one case report describing the use of percutaneous angioplasty and stent placement for left subclavian stenosis associated with pacemaker leads in a patient with ipsilateral AVF for HD (33). This was technically and clinically successful in resolving the venous hypertension, although long-term follow-up was not reported; there was no known adverse effect on pacemaker function.

CRMD leads entrapped by a venous stent or stent-graft would prove difficult or impossible to remove using laser lead extraction. Based upon this concern, recently published CRMD lead extraction guidelines

advise against placing central venous stents adjacent to CRMD leads (34). This recommendation is presented with category "C" level of evidence, based upon "consensus opinion of experts, case studies, or standard of care". This document does not offer any recommendations directly referable to ESRD patients. In order to avoid CRMD lead entrapment in cases of central venous stenosis requiring stent placement the Heart Rhythm Society recommends device lead extraction, venous angioplasty and stent placement, followed by device lead replacement through the stented vein or an alternative site. This approach may be feasible and appropriate for some patients. However, there are barriers to successful lead extraction and significant rates of procedure-related complications with attendant morbidity and mortality. One report describes four patients with CRMD lead-associated SVC stenosis who underwent laser lead extraction followed by SVC stent placement and device lead replacement (35). In this report, three of four procedures were successful; one was complicated by torn tricuspid valve leaflet chordae with acute valvular dysfunction requiring surgical valve replacement and the placement of an epicardial pacing lead. Two large series have reported results of laser lead extraction in 863 (36) and 1684 (37) patients. Successful lead extraction was achieved in 90% of cases. Complications occurred in 3%, graded as severe in 1.9%, including cardiac tamponade, hemothorax, and pulmonary embolus. Death occurred in 0.8% of cases. It was also shown that there was a significant "learning curve" with more experienced operators achieving higher success and lower complication rates. It is not known if these reported outcome and complication rates would pertain to the HD patient population, nor if the same results would be achieved in typical community practice outside of the large centers of excellence represented in these reports.

Treatment of central venous stenosis with angioplasty, stents, or stent-grafts is rarely permanently curative; restenosis is likely and repeated reinterventions are to be expected. Eleven of the 14 patients in this study (78.6%) required repeat interventions and five patients (35.7%) underwent additional central venous stent placement. Therefore, the relatively complex and high-morbidity procedures involving CRMD lead extraction prior to central venous stent placement and subsequent lead replacement would potentially need to be repeated in the event an additional stent was required for the management of recurrent venous stenosis.

The greatest concern for CRMD lead entrapment is the inability to remove the leads using laser lead extraction in the setting of endovascular infection that failed to respond to antibiotic therapy. Lead extraction in such situations would require an open surgical procedure with attendant risks, high morbidity, and mortality. It should be recognized that in cases of persistent endovascular infection, removal of the CRMD leads, entrapped or not, would offer an incomplete solution, as the retained central venous stent may also harbor infection. Effective treatment of bacteremia for central venous stent infection has been reported without removal of the stent (38).

The annual mortality rate for all United States HD patients from 1999-2001 was 23.5% (39). The rate is even higher in elderly dialysis patients with concomitant cardiac disease, diabetes, or history of sudden cardiac death (2). Long-term survival may not be an achievable goal for many of these patients. For some, the most important goals are to remain out of the hospital, minimize risks and complications of highly invasive procedures, preserve their functional AV access, and avoid the excessive morbidity of venous catheter access. Stenting of central venous stenosis associated with CRMD leads is consistent with these important goals. As such this may be viewed as a palliative approach to care, trading off theoretical risks related to possible future CRMD lead extraction versus the very real and immediate benefits of AV HD access preservation and avoidance of venous catheter access.

Our study does not shed any light on the role of stent-grafts vs. bare metal stents for the treatment of central vein stenosis. Only two patients in this study were treated with stent-grafts. One had a relatively small diameter right subclavian and brachiocephalic vein without severe angulation that could accommodate the available 10 mm diameter tracheobronchial stent-graft. The other had long segment left subclavian vein occlusion and immediate tissue prolapse and/or adherent thrombus compromising the bare metal stent lumen with angiographic evidence of persistent venous hypertension post-stent; this was treated with a stent-graft. By virtue of their open architecture bare metal stents allow ingrowth of tissues through the stent interstices leading to in-stent restenosis, particularly when over-sized (40). Stent-grafts reduce the potential for tissue ingrowth and in-stent stenosis. Whether this property translates into superior outcomes remain to be demonstrated. Larger diameters are limited in the available stent-grafts restricting their utility in central venous applications. The cost of a stent-graft is substantially greater than that of a bare metal stent but may be justifiable if superior patency and outcome can be demonstrated and a functional access be preserved.

Prevention remains the most important factor in the management of central venous stenosis. Use of CRMDs in HD patients should be judicious, carefully considering potential benefits of the device vs. other co-morbid factors, including adverse impact on existing or future AV access. Whenever possible, CRMD lead insertion and HD access should be avoided on the same side.

The left (non-dominant) arm is commonly preferred for initial HD access. Likewise the left subclavian or cephalic vein approach is preferred by many electrophysiologists for CRMD lead insertion due to favorable shock vectors (43). The use of the internal jugular vein for CRMD lead insertion has been reported in patients where other central venous access was not feasible (41) and avoids direct damage to the subclavian vein. However, the internal jugular vein approach does not spare the brachiocephalic vein so the potential for central vein stenosis remains significant. Furthermore, the jugular vein would be compromised, limiting its use for future venous HD access. Use of the iliac vein has been reported for CRMD lead insertion in patients with occluded thoracic central veins (42, 43).

It is essential to establish good cooperation and communication between cardiac electrophysiologists, vascular access surgeons, and interventional physicians responsible for the management of HD access. Careful selection of veins for the insertion of device leads and avoidance of the subclavian vein ipsilateral to HD access will minimize central vein stenosis and reduce requirements for future interventions. It should be emphasized that in all of the 14 patients in this study, the CRMD was placed prior to surgical construction of the ipsilateral AV access. When CRMD device lead-associated central vein stenosis is identified, decisions about the appropriate treatment strategy must be made in concert by the interventional physician and the electrophysiologist.

There are several important caveats and factors to consider before placing a stent for CRMD-associated central vein stenosis. Serial angioplasty without stent placement is generally benign, well-tolerated, convenient, and a reasonable alternative for most patients (20). Stent or stent-graft therapy should only be employed for lesions where angioplasty has proven to be ineffective. Furthermore, if the AV access is of poor quality, construction of a new high-quality AV access in the contralateral limb may provide the patient with a superior long term-outcome, avoiding the potential complications of entrapped CRMD leads. Age, general health, and co-morbid conditions must be considered. Extremely elderly patients and those with severe cardiac disease, cancer, or chronic nursing-home status might be best treated by the use of stents for treatment of CRMD lead-associated central vein stenosis in order to salvage an existing functional access that might reasonably be expected to last for the remainder of that patient's lifetime. Younger patients with less comorbidity and greater probability of long-term survival might be better candidates for the more invasive lead extraction and replacement approach to stenting CRMD lead-associated venous stenosis. Coordination of care with the patient's nephrologist and cardiac electrophysiologist is essential in order to properly weigh all the relevant clinical issues and procedure alternatives. It is also essential to recognize that central vein stent or stent-grafts are easily placed but nearly impossible to remove, such that any ramifications of CRMD lead entrapment are immediate and permanent. If there is any doubt about these considerations it is inadvisable to place a stent.

CONCLUSION

Placement of central venous stents for CRMD lead-associated stenosis or occlusion is technically feasible with high procedure success and low complication rates. Patency rates are similar to those reported in other series of central venous stents. There was no observed effect on CRMD function. Stenting should be considered for the treatment of symptomatic CRMD associated central vein stenosis or occlusion in selected HD patients who cannot be effectively managed with angioplasty alone.

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