

CARDIOVASCULAR DISEASE

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Wilderness is not a luxury but a necessity of the human spirit. EDWARD ABBEY, Desert Solitaire his year's chapter on cardiovascular disease in ESRD patients covers a number of topics new to the ADR. The Cardiovascular Special Studies Center (CVSSC) has, for example, examined sudden cardiac death (SCD) in past ADRs, describing its epidemiology and preventative treatment — notably the use of implantable cardioverter defibrillators (ICDS). In this ADR we present new data on the occurrence of SCD in incident dialysis patients.

It has been appreciated for many years that the mortality rate in patients starting dialysis is considerably higher than in the prevalent dialysis population, but few data have been available on cause-specific mortality, particularly on SCD. On the next page we show that, despite the heightened rate of SCD in incident patients, the overall contribution of arrhythmic mechanisms as a percentage of attributable mortality is actually lower in incident than in prevalent patients. Twenty-four percent of incident patient deaths are attributed to arrhythmic mechanisms, compared to 30 percent in the prevalent population.

Another important issue is the relative imprecision of the method used to estimate SCD rates. In the 2006 ADR, we presented a new method designed to increase the level of precision above that obtained by using only data from the ESRD Death Notification form (CMS-2746). Here we illustrate long-term temporal trends in SCD, comparing the "new" or "complex" (Pun et al.) method to the "old" or "simple" method.

Expanding the analyses of prior ADRS on the epidemiology of SCD, we frame these data with information on new therapies designed to reduce the risk of SCD. We have previously looked at the use of ICDS and cardiac resynchronizationdefibrillator devices (CRT-DS), and at survival in the ESRD population following their implantation. The use in ESRD patients of wearable cardioverter defibrillators (wCDS), a "niche" therapy available in the U.S. for a decade, has, however, received little attention. In this ADR we present the first long-term survival data for a small number of dialysis patients who have received wCDS.

One long-time interest of the CVSSC is the persistently high mortality following AMI in dialysis patients. Despite improvements in survival after AMI in the general population, the two-year mortality rate among 2008 dialysis patients was 71.5 percent, nearly identical to the 73 percent reported fourteen years ago (Herzog et al.). Later in the chapter we examine fatal versus non-fatal AMI in ESRD patients; the estimation of fatal and non-fatal cardiovascular endpoints is an important issue on which there has been little data published.

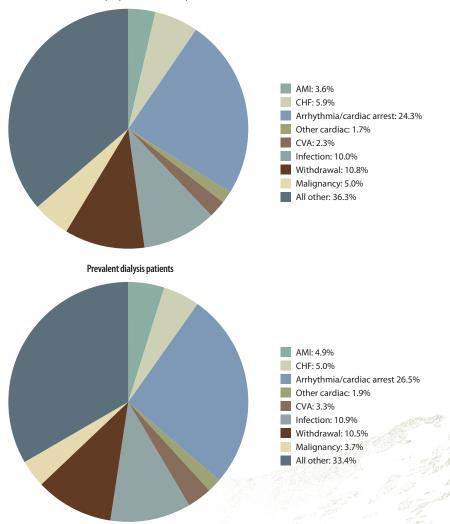
Non-invasive and invasive cardiac evaluations are an important component of the care of ESRD patients, with respect both to diagnosis and treatment in dialysis patients and to the pre-transplant evaluation of renal transplant candidates. Guideline 1.1a of the National Kidney Foundation KDOQI Clinical Practice Guidelines for Cardiovascular Disease in Dialysis Patients recommends that a resting echocardiogram "be performed in all patients at the initiation of dialysis (pediatric or adult), once the patient has achieved dry weight, ideally within one to three months of dialysis initiation." We present data addressing the use of echocardiography in incident dialysis patients, and on stress testing and angiography in incident dialysis patients and patients wait-listed for a renal transplant.

Finally, a key component of the treatment of cardiovascular disease in ESRD patients is their medical therapy. On the last spread we look at medication use and at survival associated with treatment. **» Figure 4.1;** see page 435 for analytical methods. *Incident & prevalent dialysis patients, 2008–2010.*

cardiovascular disease introduction



Incident dialysis patients: first 180 days

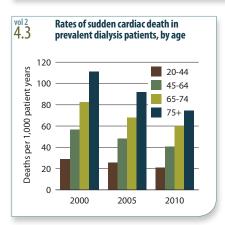


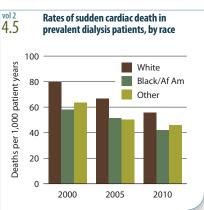
This figure uses the old/simple method and the new/complex method to estimate SCD rates in prevalent dialysis patients. The complex method yields a consistently lower rate for the past decade, an important consideration in clinical trial design. One important factor in this difference is the number of patients withdrawn from dialysis, a major cause of death which does not figure in clinical trials in the general population. » Figure 4.2; see page 435 for analytical methods. Period prevalent dialysis patients, age 20 & older.

Between 2000 and 2010, the rate of SCD in hemodialysis patients fell from 70 to 50 per 1,000 patient years, a decline mirrored in the peritoneal dialysis population. The largest absolute decline has occurred in the populations at highest risk of sudden cardiac death - those of older age, white race, or with diabetes. In patients 75 or older, for example, the rate fell from 111 to 75. There are many potential explanations for this striking temporal trend, but one possible contributor is the rapid expansion in the use of beta blockers. » Figures 4.3-6; see page 435 for analytical methods. Period prevalent dialysis patients, age 20 & older; unadjusted, & using the complex method.

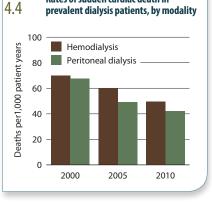
vol 2 4.2 Rates of sudden cardiac death in prevalent dialysis patients, by method of estimation 100 Deaths per 1,000 patient years 80 Simple method 60 Complex method 40 20 0 91 95 96 97 98 99 00 01 02 03 04 05 06 07 08 09 10 92

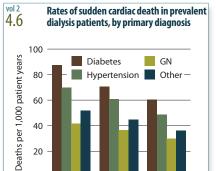
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Rates of sudden cardiac death in





2005

2010

0

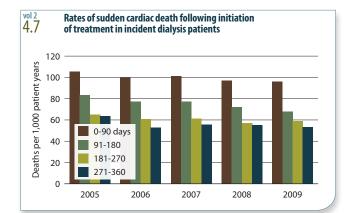
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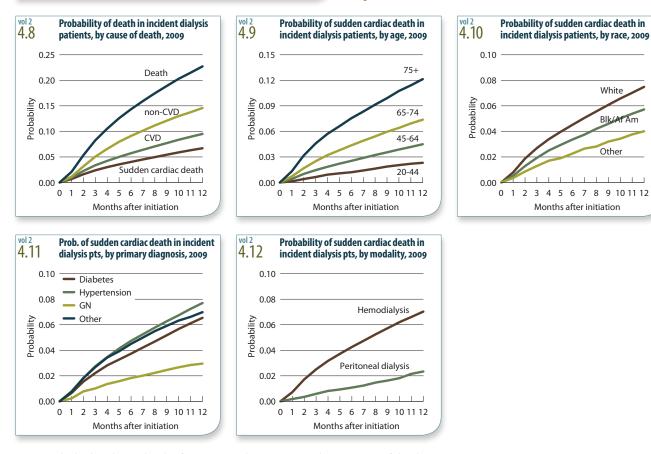


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cardiovascular disease sudden cardiac death in incident & prevalent dialysis patients

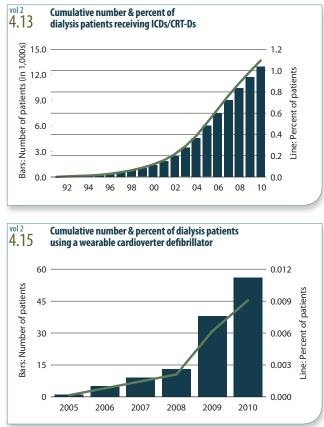


In comparison to the marked reduction in sCD in prevalent dialysis patients (Figures 4.3–6), the reduction in the rates of sCD in the first 90 days of therapy is relatively modest. Between 2005 and 2009 this rate fell only 10 percent, from 105 to 96. The first 90 days after dialysis initiation constitute a period of heightened sCD risk. **» Figure 4.7**; see page 435 for analytical methods. *Incident dialysis patients age 20 & older; unadjusted, & using the simple method.*



Even with the heightened risk of sCD in incident patients, the majority of deaths in the first year of dialysis are non-cardiovascular. White patients, not surprisingly, have the highest risk by race of sCD; it is surprising, however, that patients with diabetic ESRD do not have the highest risk by diagnosis, as they do in the prevalent population.

While the risk of SCD is fairly uniform for peritoneal dialysis patients in the first year of therapy, the first 90 days are a period of increased risk for hemodialysis patients. It is tempting to attribute this difference to the acute hemodynamic stress associated with hemodialysis initiation and the much larger acute potassium shifts accompanying thrice-weekly hemodialysis in patients who may have been chronically hyperkalemic before initiation. It would be very interesting if data of this type were also available on patients receiving frequent or long-duration dialysis, as a lower risk of SCD in incident dialysis patients might be anticipated. **»** Figures 4.8–12; see page 435 for analytical methods. *Incident dialysis patients age 20 & older; simple method*.



Figures 4.13–14 document both the increasing numbers of dialysis patients receiving ICD/CRT-D devices and the overall decline in use after 2006, similar to that seen in the general population. From 1991 through 2010, we estimate that 12,984 unique dialysis patients received an ICD/CRT-D device, with 3,191 of these patients receiving a CRT-D device.

Two-year mortality in dialysis patients after the implantation of ICDS/CRT-DS is high, reaching 53 percent following implantation for primary prevention and nearly 58 percent after implantation for secondary prevention. The two-year mortality for a transplant patient in the primary prevention group, in contrast, is 34 percent.

While wCDs have been used in over 60,000 U.S. patients

in the last decade, there are few data on the use of this device

in dialysis patients. Figures 4.15 and 4.17 present data on these

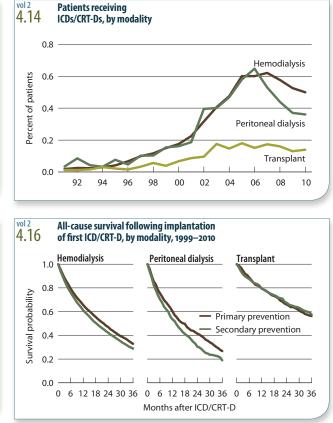
patients and their associated survival. » Figures 4.13–17; see page 435 for analytical methods. Period prevalent patients: dialysis patients (4.13); dialysis & transplant patients in each year (4.14); dialysis patients (4.15); dialysis & transplant patients receiving their first ICDs/CRT-Ds in 1999–2010 (4.16); dialysis patients receiving their

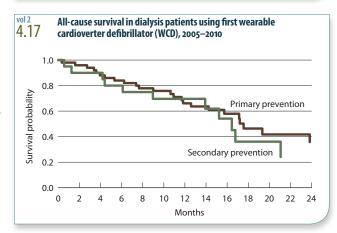
first wCDs in 2005-2010 (4.17).

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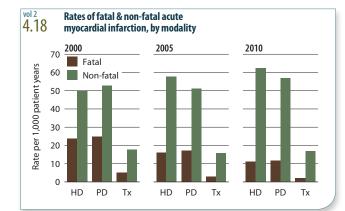




CARDIOVASCULAR DISEASE defibrillators & survival after a cardiac event

4.a Rates (per 1,000 patient years) of cardiovascular events & procedures

	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
AMI															
Hemodialysis	53.8	56.5	61.8	70.0	73.6	77.4	80.9	80.5	76.4	73.9	70.2	70.9	75.0	72.3	73.6
Peritoneal dialysis	66.0	67.9	72.7	74.3	77.6	79.3	79.9	76.7	72.1	68.4	65.7	68.1	67.3	67.7	68.6
Transplant	20.0	20.4	21.8	22.0	22.6	23.1	23.6	23.3	21.2	18.8	16.5	16.9	18.3	17.4	18.8
CVA/TIA															
Hemodialysis	174.5	179.6	181.4	178.7	186.1	192.6	200.6	200.9	212.6	205.8	201.3	199.9	206.7	201.7	205.2
Peritoneal dialysis	158.0	162.9	160.6	152.7	151.9	157.4	157.6	144.2	152.7	142.7	140.0	129.6	139.1	137.4	139.9
Transplant	47.0	51.5	52.2	50.0	51.8	53.2	56.8	22.9	59.9	60.9	58.5	58.3	66.4	65.0	70.5
Peripheral arterial disea	ase														
Hemodialysis	477.7	462.0	463.6	454.3	460.8	474.7	483.5	478.6	502.5	503.5	492.2	490.9	515.6	511.2	525.6
Peritoneal dialysis	317.5	312.1	307.8	297.0	303.4	304.0	303.5	293.5	312.6	303.3	285.4	282.0	281.4	280.8	284.2
Transplant	119.3	123.7	123.7	122.3	130.1	132.4	140.3	74.2	144.8	146.0	141.1	141.4	152.6	149.7	161.4
Congestive heart failur	e														
Hemodialysis	554.8	573.3	578.8	574.9	583.0	611.6	636.4	643.3	682.0	688.9	677.7	681.1	686.0	677.4	696.3
Peritoneal dialysis	410.7	396.2	402.6	383.9	397.0	393.9	393.4	392.3	421.2	404.3	409.2	385.5	362.9	352.7	359.2
Transplant	102.5	112.3	121.8	126.1	133.7	138.3	145.2	65.6	152.3	153.1	144.5	142.5	153.6	150.6	163.3
Revascularization: PCI															
Hemodialysis	17.8	18.9	21.4	23.9	25.7	29.0	31.3	33.5	36.5	37.3	37.4	34.0	35.3	36.5	38.2
Peritoneal dialysis	17.9	19.5	22.1	25.3	27.2	29.9	32.4	35.8	39.5	38.6	41.2	36.9	38.6	41.5	41.5
Transplant	10.8	11.9	12.6	12.1	12.8	13.1	14.2	14.2	15.3	14.2	13.3	12.1	12.7	12.1	13.6
Revascularization: CAB	G														
Hemodialysis	11.9	12.7	12.5	13.3	13.6	12.7	13.3	12.6	12.0	11.5	10.7	10.9	10.5	10.7	10.5
Peritoneal dialysis	15.2	15.3	15.2	13.8	16.2	15.9	16.6	15.0	14.5	16.3	14.4	13.3	14.2	14.7	14.8
Transplant	7.1	6.9	7.7	7.1	6.5	6.7	6.2	5.8	5.2	5.1	4.4	3.9	4.0	3.5	3.9



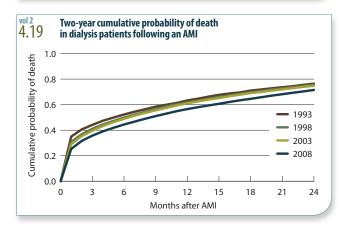


Table 4.a presents a 15-year temporal analysis of cardiovascular conditions and cardiac revascularization procedures in ESRD patients, showing congestive heart failure and peripheral arterial disease as the two conditions with the highest prevalent rates.

Figures 4.18–19 provide new data on the epidemiology of AMI in ESRD patients, showing, for example, the apparent, counterintuitive occurrence of declining rates of fatal AMI and the simultaneous growth in rates of non-fatal AMI. It is tempting to attribute the increase in non-fatal AMI to the use of increasingly more sensitive biomarkers for diagnosis, such as cardiac troponins. The decline in fatal AMI may also be related to improvements in cardiovascular outcomes in ESRD patients, as well as to changing definitions (described in the appendix).

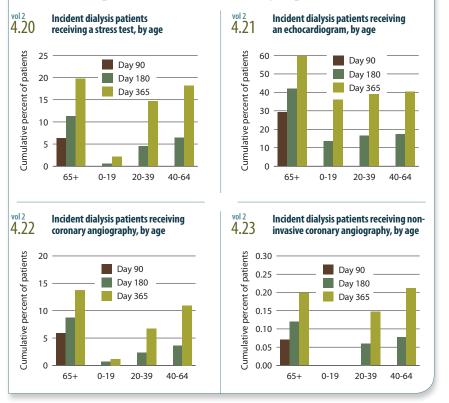
Since 1993, outcomes for dialysis patients after AMI have been consistently poor. One cause for optimism, however, is the improvement in 30-day mortality, from 35 percent in 1993 to 25 percent in 2008. While initial treatment has probably improved patient outcomes, much attention needs to be directed to long-term (i.e., post-discharge) treatment and survival. **» Table 4.a & Figures 4.18–19**; see page 435 for analytical methods. *Point prevalent ESRD patients on January 1 of each year, age 20 & older; unadjusted (4.a & 4.18). Period prevalent dialysis patients with first AMI in the year, unadjusted (4.19).* This table is a snapshot of echocardiography use in 2010 incident dialysis patients, intended to frame the 2005 KDOQI guideline. Because of Medicare eligibility, claims data for the first 90 days following dialysis initiation are available only for patients age 65 and older. Approximately half of these patients receive an echocardiogram in the first year after initiation of dialysis. In patients younger than 65 (including pediatric patients), about one in four receive an echocardiogram in the period from 90 days to one year after dialysis initiation. **» Table 4.b;** see page 435 for analytical methods. *Incident dialysis patients, 2010.*

4.b Percent of incident dialysis patients receiving first echocardiograms, 2010

	5				
	Total	First 90 days		Day 90 to 1 ye	ar
	N	N	Percent	N	Percent
Age 65+	32,733	9,548	29.2	6,437	19.7
0-19	413			91	22.0
20-39	3,900			995	25.5
40-64	22,248			5,800	26.1
Age 65+					
White	24,189	7,069	29.2	4,785	19.8
Black/Af Am	6,916	2,011	29.1	1,368	19.8
Other	1,628	468	28.7	284	17.4

Among 2010 incident dialysis patients age 65 and older, the cumulative percentage receiving an echocardiogram in the first year reached 60 percent, compared to 20 and 14 percent for stress tests and invasive coronary angiography, but only 0.2 percent for non-invasive angiography. The very low rate of non-invasive CT coronary angiography use probably reflects both the new Medicare reimbursement for this procedure and the technical difficulty of performing it in dialysis patients, due to the large burden of coronary calcification. » Figures 4.20-23; see page 435 for analytical methods. Incident dialysis patients, 2010.

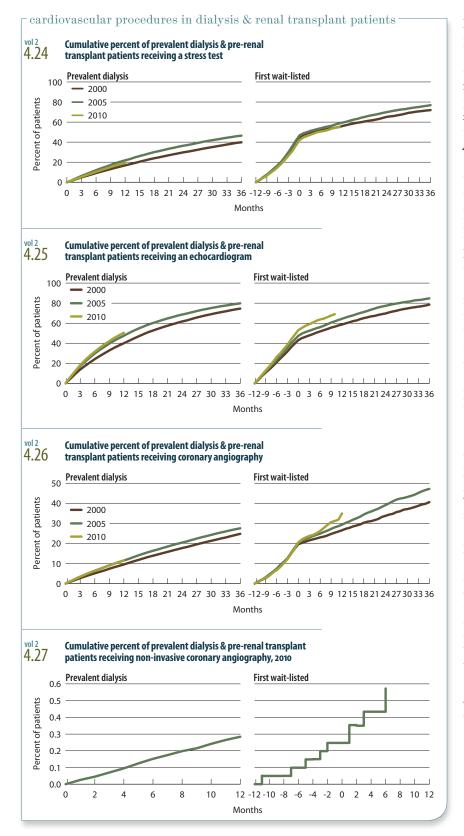
cardiovascular procedure use in incident dialysis patients -



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In 2000, approximately 17 percent of prevalent dialysis patients received a stress test in the first year of therapy, compared to 22 percent in 2005 and 19 percent in 2010. Forty-two percent of patients wait-listed for a transplant in 2010 had a stress test in the year prior to listing, a modest reduction from the 47 percent seen in patients listed in 2005.

The use of echocardiography, in contrast, has been on the rise. In prevalent dialysis patients, the cumulative percentage receiving an echocardiogram has increased from 40 percent in 2000 to 48 and 51 percent in 2005 and 2010. In the year prior to wait-listing for a transplant, the number has increased from 43 percent in 2000 to 48 percent in 2005 and 53 percent in 2010. With the small decline in the use of stress testing in dialysis patients, one explanation might be an increase in the use of coronary angiography, but data here show that very few prevalent dialysis patients or patients wait-listed for a transplant receive non-invasive CT coronary angiograms.

One issue related to the use of angiography in the screening of renal transplant candidates has been the issue of preemptive transplantation. Patients with declining renal function not yet requiring dialysis therapy may be considered for both preemptive renal transplantation or, lacking an available kidney donor, "preemptive" wait-listing. It is likely that concerns related to the risk of contrast nephropathy, and the precipitation of AKI requiring emergency dialysis, still temper the use of diagnostic coronary angiography in patients being screened for renal transplantation but who do not yet require dialysis. » Figures 4.24–27; see page 435 for analytical methods. Point prevalent dialysis patients & Medicare enrollees wait-listed for the first time.



Cardiovascular disease & pharmacological 4.c interventions, by diagnosis & modality (row percent)

vol 2

	2007		Beta	Clopid-			Amio	2010		Beta	Clopid-			Amio-
	N	ACEI/ARB	blocker	ogrel	Warfarin	Statin	darone	Ν	ACEI/ARB	blocker	ogrel	Warfarin	Statin	darone
CHF														
Hemodialysis	56,199	43.5	56.7	17.4	12.2	33.1	5.3	59,664	46.6	66.0	21.7	14.0	42.7	6.3
Peritoneal dialysis	1,924	41.2	57.9	16.6	12.3	37.0	5.0	1,934	45.2	67.2	21.2	13.1	48.6	6.7
Transplant	3,811	41.4	70.0	14.5	17.3	50.4	4.1	4,792	42.2	76.3	16.7	19.4	58.5	4.5
AMI														
Hemodialysis	4,271	56.3	75.0	47.2	11.5	54.8	7.3	4,986	55.5	76.9	51.2	13.2	61.9	7.7
Peritoneal dialysis	200	47.5	78.5	53.5	9.5	56.5	8.5	216	52.8	78.2	61.1	12.5	69.9	6.0
Transplant	264	54.2	84.8	49.2	18.6	69.7	3.8	348	48.6	87.1	54.0	14.9	77.6	5.5
PAD														
Hemodialysis	47,291	39.5	51.6	19.3	12.2	34.8	4.3	50,148	41.9	59.3	23.9	13.6	43.6	5.0
Peritoneal dialysis	1,578	36.9	49.3	22.6	9.5	41.0	3.9	1,584	40.6	56.4	26.8	11.1	53.2	3.3
Transplant	4,387	39.9	59.9	15.3	13.2	51.0	2.1	5,237	41.5	67.6	19.7	13.9	58.0	2.2
CVA/TIA														
Hemodialysis	20,229	43.5	55.8	23.2	12.7	37.8	4.7	20,293	46.4	63.4	27.2	13.5	47.8	5.2
Peritoneal dialysis	719	41.6	55.5	23.9	11.0	47.0	4.5	787	46.0	59.2	27.2	14.4	51.5	4.1
Transplant	1,738	40.5	61.4	20.9	15.8	54.1	2.2	2,076	41.2	66.6	22.6	16.9	63.3	2.9
AFIB														
Hemodialysis	18,938	35.6	55.3	15.8	34.5	33.2	15.8	21,975	37.2	62.9	18.9	38.8	43.2	17.8
Peritoneal dialysis	625	31.0	55.0	16.3	39.8	38.7	17.8	791	33.9	63.8	15.4	43.4	50.7	19.2
Transplant	1,870	37.7	65.1	9.0	47.8	47.0	10.2	2,840	42.6	74.4	10.3	54.0	58.2	11.9
ICD/CRT-D														
Hemodialysis	734	55.3	72.8	29.3	19.6	45.6	13.1	610	58.0	76.6	30.3	22.1	47.5	17.4
Peritoneal dialysis	31	54.8	77.4	19.4	19.4	41.9	19.4	26	53.8	88.5	19.2	11.5	53.8	26.9
Transplant	48	56.3	89.6	27.1	33.3	60.4	8.3	46	52.2	87.0	26.1	34.8	76.1	15.2
Revascularization: PO	21													
Hemodialysis	3,507	55.0	76.0	83.1	9.5	60.5	5.2	4,214	54.8	77.4	83.5	9.6	67.8	5.6
Peritoneal dialysis	197	49.7	72.6	85.8	4.1	59.9	6.1	217	47.5	74.2	82.0	6.5	71.4	2.8
Transplant	296	49.7	76.4	86.5	12.2	70.6	3.4	407	49.9	82.1	83.3	8.1	76.9	1.2
Revascularization: C	ABG													
Hemodialysis	615	58.0	77.2	32.2	10.1	64.7	17.6	687	55.7	83.3	38.3	12.4	70.6	17.2
Peritoneal dialysis	38	57.9	84.2	34.2	21.1	65.8	21.1	54	46.3	81.5	44.4	9.3	70.4	20.4
Transplant	51	58.8	82.4	31.4	15.7	68.6	17.6	73	50.7	90.4	28.8	27.4	83.6	31.5
No cardiac event														
Hemodialysis	55,043	44.2	51.8	8.2	6.8	28.3	1.0	63,847	46.9	58.1	9.4	6.6	33.9	1.1
Peritoneal dialysis	6,320	43.5	47.5	5.4	3.6	33.7	0.6	6,840	49.0	55.9	5.9	4.3	39.7	0.6
Transplant	27,035	41.9	53.9	3.7	4.7	47.6	0.4	31,699	41.8	58.6	4.7	4.8	51.1	0.3

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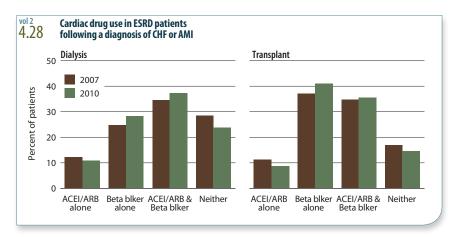
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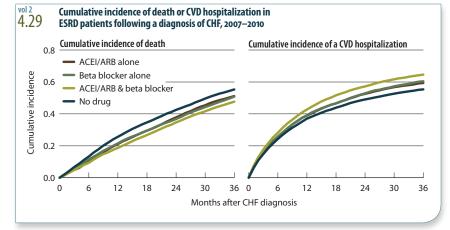
Two-thirds of dialysis patients diagnosed with CHF in 2010 received a beta blocker, while 47 percent of hemodialysis patients with this diagnosis received an ACEI/ARB. Beta blockers were used by more than three-quarters of ESRD patients with an AMI during 2010 and, remarkably, by 58 percent of hemodialysis patients with no cardiovascular diagnosis or intervention. At least with respect to medical therapy with beta blockers, if therapeutic nihilism in dialysis patients is not dead, it would certainly appear to be moribund. This is not to say that ESRD patients uniformly receive therapies to the same degree as patients in the general population, but, at least with respect to certain evidence-based therapies, such as beta blockers, the gap in utilization is markedly smaller than it was a decade ago. The use of warfarin in hemodialysis patients with atrial fibrillation remains relatively low, perhaps reflecting concerns related to hemorrhagic risk in these patients. And given the

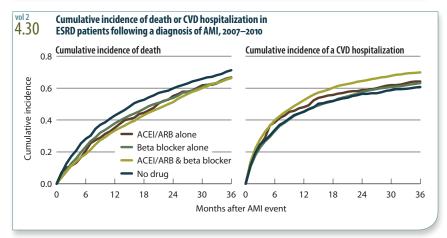
relative paucity of data on amiodarone therapy in this population, the rates of amiodarone use for atrial fibrillation are perhaps higher than would be expected.

Finally, despite the publication of the 4D and AURORA trials, there has been no discernible reduction in the use of statin therapy in u.s. dialysis patients. To the contrary, even in those without identified prevalent cardiovascular illness, 28 percent of hemodialysis patients and 34 percent of peritoneal dialysis patients in 2007 received statins, compared to 34 and 40 percent in 2010. In the population qualifying for secondary prevention (e.g., those with an AMI), the use of statin therapy in hemodialysis patients increased from 55 percent in 2007 to 62 percent in 2010. » Table 4.c; see page 435 for analytical methods. January 1 point prevalent patients with Medicare Parts A, B, & D enrollment, with a first cardiovascular diagnosis or procedure in the year.

CARDIOVASCULAR DISEASE medication & survival in ESRD patients with cardiovascular disease







After AMI or a diagnosis of CHF, the number of ESRD patients receiving a beta blocker rose from 59 percent in 2007 to 65 percent in 2010. Use of ACEIS/ARBS declined slightly.

Data on the incidence of death and cardiovascular hospitalization following AMI or a diagnosis of CHF should be interpreted with caution, as there may be an element of selection bias. It is interesting to note, however, that the highest risk of death occurs in patients receiving no therapy. After a diagnosis of CHF, mortality among patients receiving combined therapy with ACEIS/ARBs and beta blockers was 19 percent, compared to 26 percent among those receiving no therapy; following AMI, these rates were 33 and 43 percent.

Different patterns occur for cardiovascular disease hospitalizations. It is possible that the increased incidence of hospitalizations may paradoxically relate in part to improved survival in patients receiving these beneficial therapies. **» Figures 4.28–30;** see page 435 for analytical methods. *January 1 point prevalent ESRD patients* with Medicare Parts A, B, & D enrollment, with a first diagnosis of CHF or AMI in the year.



CARDIOVASCULAR OUTCOMES

outcomes at two years following a diagnos	sis of CHF (cumulativ	e incidence; Figu	re 4.29)	
death » AG	сеі/акв · 0.38 » beta ł	olocker · 0.37 » b	oth · 0.35 » neithe	er · 0.43
cardiovascular hospitalization	· 0.53	· 0.53	· 0.57	· 0.49
outcomes at two years following a diagnos	sis of AMI (cumulativ	e incidence; Figu	re 4.30)	
death » AG	сеі/акв · 0.55 » beta l	olocker · 0.54 » b	oth · 0.51 » neithe	er · 0.60
cardiovascular hospitalization	· 0.59	· 0.58	· 0.64	· 0.56
MEDICATION USE				
pharmalogical intervention following a di	agnosis of CHF, 2010	(percent of patie	nts on medication	; Table 4.c)
hemodialysis » AG	сеі/акв · 46.6 » beta ł	olocker · 66.0 » c	lopidogrel · 21.7 »	statin · 42.7
peritoneal dialysis	· 45.2	· 67.2	· 21.2	· 48.6
transplant	· 42.2	· 76.3	· 16.7	· 58.5
pharmalogical intervention following a di	iagnosis of AMI, 2010	(percent of patie	nts on medication	; Table 4.c)
	CEI/ARB · 55.6 » beta ł			
peritoneal dialysis	· 52.8	· 78.2	· 61.1	· 69.9
transplant	· 48.6	· 87.1	· 54.0	· 77.6
pharmalogical intervention following a di	agnosis of CVA/TIA (1	percent of patien	ts on medication;	Table 4.c)
	CEI/ARB · 46.4 » beta			
			1 0	

nemodal ysis* Nell/Mil40.4* Seta blocker69.4* eloptogref27.2* statil47.5peritoneal dialysis \cdot 46.0 \cdot 59.2 \cdot 27.2 \cdot 51.5transplant \cdot 41.2 \cdot 66.6 \cdot 22.6 \cdot 63.3



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CARDIOVASCULAR DISEASE SUMMARY