

Short- and Long-Term Clinical Outcomes of Coronary Drug-Eluting Stent Recipients Presenting with Chronic Renal Disease

**Gregory J. Mishkel, MD, †Joji J. Varghese, MD, †Anna L. Moore, MPH, **Frank Aguirre, MD, †Stephen J. Maxwell, MS, **Marc Shelton, MD

ABSTRACT: Background. Randomized trials of drug-eluting stents (DES) excluded patients with severe renal insufficiency. We sought to evaluate the impact of baseline renal function on clinical outcomes in recipients of coronary DES. **Methods.** We retrospectively reviewed our hospital databases to identify consecutive patients who underwent DES implantations between May 2003 and December 2004, subgrouped among 4 ranges of glomerular filtration rate (GFR) between ≥ 90 ml/min and < 30 ml/min, in 30 ml/min decrements, and 1 group treated with long-term dialysis. Clinical follow up was obtained at 6 months, 1 year and annually thereafter. **Results.** Our study group included 2,758 patients with long-term outcomes recorded over a mean follow up of 706 ± 273 days. The rates of in-hospital adverse events increased significantly as GFR decreased, though no major adverse event occurred among the dialyzed patients. Actuarial survival analyses up to 2 years revealed significant between-groups differences in rates of major adverse cardiac events (MACE) and death (both $p < 0.001$), while the differences in target vessel revascularization (TVR) rates did not reach statistical significance ($p = 0.069$). By Cox regression analysis, a GFR < 60 ml/min remained a significant predictor of 2-year mortality ($p < 0.001$) and MACE ($p < 0.001$), but not TVR ($p = 0.839$). **Conclusions.** In conclusion, low rates of TVR were observed over 2 years in DES recipients with a wide range of renal function. Low rates of TVR were countered by high rates of death and MACE among renally insufficient patients over the long term.

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Chronic renal disease (CRD) is a common health concern in wealthy countries, with approximately 20 million American adults currently affected.¹ While the association between renal insufficiency and increased risk of adverse non-fatal and fatal cardiovascular events has been firmly established,²⁻⁵ the relationship between renal function and risk of restenosis after coronary artery stenting is less certain.^{6,7}

Furthermore, a recent U.S. Food and Drug Administration panel examining the safety of drug-eluting stents (DES)

focused on the proportion of current recipients who would have been excluded from the original randomized trials, and showed the superiority of DES over bare-metal stents (BMS).⁸ The majority of patients enrolled in the DES landmark pivotal trials had preserved renal function.⁹⁻¹² The few studies of the effects of CRD on clinical outcomes after implantation of DES have included small numbers of patients, and have been limited by: (a) ≤ 1 -year follow-up periods; (b) the exclusive use of a single stent type; or (c) the exclusion of patients with severe renal insufficiency.¹³⁻¹⁵

These limitations prompted us to analyze the relationship between baseline renal function and in-hospital and long-term clinical outcomes in a large series of consecutive patients who underwent implantations of DES. We therefore sought to review our database with the following goals: (1) to report 2-year clinical outcomes of a large cohort of DES patients; (2) to report outcomes based on the degree of renal insufficiency, including dialysis; (3) to compare sirolimus versus paclitaxel outcomes.

Patient Population and Methods

Our retrospective review of our hospital databases identified 2,758 consecutive patients who underwent DES placement in our tertiary care medical center between May 1, 2003 and December 31, 2004, and who met the following criteria: (a) underwent a first DES procedure; (b) did not have a BMS implanted in that procedure; and (c) a preprocedural measurement of serum creatine was available. The study protocol was approved by the local Investigational Review Board.

Renal function assessment. Glomerular filtration rate (GFR) was calculated using the Cockcroft-Gault formula $[(140 - \text{age}) (\text{weight in kg}) (0.85 \text{ for women}) / (72 \times \text{serum creatine})]$,¹⁶ from measurements of height, weight and serum creatine (mg/dl) made before the procedure, and retrospectively obtained by chart review. Patients were stratified into 5 groups according to their renal function: (1) GFR ≥ 90 ml/min (normal function); (2) < 90 and ≥ 60 ml/min (mild insufficiency); (3) < 60 and ≥ 30 ml/min (moderate insufficiency); (4) < 30 ml/min and not on dialysis (severe insufficiency); and (5) renal failure treated with dialysis.¹⁷ The size of the severe renal insufficiency group was relatively small ($n = 65$), as was the dialysis group ($n = 23$). Therefore, for selected analyses, all patients with a GFR ≥ 60 ml/min (normal renal function) were compared with all patients with a GFR < 60 ml/min (chronic renal disease) who were not treated with long-term dialysis.

From the *Prairie Heart Institute at St. John's Hospital, Springfield, Illinois; †Prairie Education & Research Cooperative, Springfield, Illinois; and ‡Southern Illinois University School of Medicine, Springfield, Illinois.

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Address for correspondence: Gregory J. Mishkel, MD, Prairie Cardiovascular Consultants, Ltd., Prairie Heart Institute at St. John's Hospital, P.O. Box 19420, Springfield, IL 62794-9420. E-mail: gmishkel@prairieheart.com

Table 1. Demographic, clinical and procedural characteristics of the study subgroups.

Demographic and Clinical Characteristics	Glomerular Filtration Rate (ml/min)					p-Value
	≥ 90 (n = 1,316)	89–60 (n = 777)	59–30 (n = 577)	< 30 (n = 65)	Dialysis (n = 23)	
Serum creatine, mg/dl (mean ± SD)	0.9 ± 0.2	1.0 ± 0.2	1.2 ± 0.4	1.9 ± 0.8	6.3 ± 2.9	< 0.001
Age, years (mean ± SD)	58.2 ± 10.1	70.6 ± 8.9	77.5 ± 7.3	82.3 ± 8.9	66.9 ± 12.4	< 0.001
Weight, kg (mean ± SD)	98.7 ± 20.5	83.5 ± 15.0	72.8 ± 13.9	61.7 ± 13.1	73.0 ± 17.0	< 0.001
Men	970 (73.7)	490 (63.1)	241 (41.8)	11 (16.9)	12 (52.2)	< 0.001
Diabetes	413 (31.4)	222 (28.6)	152 (26.3)	13 (20.0)	15 (65.2)	< 0.001
Anemia	167 (12.8)	175 (22.7)	237 (41.3)	36 (55.4)	15 (65.2)	< 0.001
Current smoker	444 (33.7)	133 (17.1)	62 (10.7)	4 (6.2)	6 (26.1)	< 0.001
Acute coronary syndrome:	770 (58.5)	396 (51.0)	337 (58.4)	43 (66.2)	14 (60.9)	0.004
Unstable angina	399 (30.3)	240 (30.9)	200 (34.7)	24 (36.9)	9 (39.1)	ns
Non-ST-elevation myocardial infarction	209 (15.9)	104 (13.4)	103 (17.9)	13 (20.0)	4 (17.4)	< 0.001
ST-elevation myocardial infarction	162 (12.3)	52 (6.7)	34 (5.9)	6 (9.2)	1 (4.3)	< 0.001
History of:						
Congestive heart failure	63 (4.8)	61 (7.9)	96 (16.6)	18 (27.7)	9 (39.1)	< 0.001
Peripheral vascular disease	107 (8.1)	102 (13.1)	110 (19.1)	14 (21.5)	10 (43.5)	< 0.001
Cerebrovascular disease	86 (6.5)	121 (15.6)	117 (20.3)	15 (23.1)	5 (21.7)	< 0.001
Myocardial infarction	357 (27.1)	204 (26.3)	184 (31.9)	20 (30.8)	6 (26.1)	ns
Percutaneous coronary intervention	402 (30.5)	256 (32.9)	181 (31.4)	17 (26.2)	8 (34.8)	ns
Coronary artery bypass graft surgery	274 (20.8)	208 (26.8)	187 (32.4)	16 (24.6)	8 (34.8)	< 0.001
Procedural Characteristics						
Glycoprotein IIb/IIIa inhibitor use	1,018 (77.4)	568 (73.1)	395 (68.5)	38 (58.5)	14 (60.9)	< 0.001
Sirolimus-eluting stent use*	1,125 (85.5)	680 (87.5)	483 (83.7)	56 (86.2)	21 (91.3)	ns
Paclitaxel-eluting stent use*	200 (15.2)	102 (13.1)	100 (17.3)	10 (15.4)	2 (8.7)	ns
Number of diseased vessels (mean ± SD)	1.9 ± 0.8	2.0 ± 0.8	2.2 ± 0.8	2.0 ± 0.8	2.2 ± 0.9	< 0.001
One	497 (37.8)	251 (32.3)	157 (27.2)	23 (35.4)	7 (30.4)	-
Two	410 (31.2)	231 (29.7)	171 (29.6)	19 (29.2)	4 (17.4)	-
Three	409 (31.1)	295 (38.0)	249 (43.2)	23 (35.4)	12 (52.2)	-

Unless otherwise specified, values indicate number (%) of patients in the corresponding group.
P-value compares the distribution across the 5 renal function groups.
*Sirolimus- and paclitaxel-eluting stents were both implanted in the same procedure in 21 patients.

Interventional procedures. PCIs were performed according to the practices and preferences of each operator, including the administration of intraprocedural heparin or bivalirudin and the use of a glycoprotein (GP) IIb/IIIa inhibitor. After having received a first 325 mg dose prior to the procedure, all patients were advised to continue treatment with aspirin indefinitely. Clopidogrel, 300–600 mg, was administered at the time of PCI, and continued for ≥ 6 months after DES implantation. Quantitative coronary angiographic measurements were performed using a computer-based edge-detection system (*HeartLab, Inc., Westerly, Rhode Island*).

Clinical follow up and study endpoints. The procedural and in-hospital outcome data were obtained from our American College of Cardiology National Cardiovascular Data Registry and Society of Thoracic Surgeons databases. Patients undergoing implantation of DES are routinely followed at our institution at 6 months, 1 year and annually thereafter by means of telephone contact with the patient or referring physician, mailed survey, electronic chart review and/or

review of death certificates. The 1- and 2-year study endpoints were all-cause mortality, target vessel revascularization (TVR), and major adverse cardiac events (MACE). TVR was defined as reintervention on the stented segment for clinical manifestations consistent with recurrent myocardial ischemia or > 70% stenosis on follow-up angiogram. Myocardial infarction (MI) was defined as the occurrence of chest pain accompanied by new, typical electrocardiographic changes and a rise in creatine kinase-MB above 3-fold the upper normal limit. Cardiac enzymes are not drawn systematically at our institution, but rather at the onset of chest pain and/or electrocardiographic (ECG) changes. MACE was a composite endpoint of all-cause mortality, non-fatal MI and TVR. Procedure-induced or aggravated renal dysfunction was defined as: (a) a postprocedural increase in serum creatine to > 2.0 mg/dl; (b) a ≥ 50% increase over an abnormal baseline value; or (c) new requirement for dialysis. Vascular complications included: (a) blood loss at the point of vascular access requiring a blood transfusion, or prolongation of hospitalization, or

Table 2. Lesion characteristics of each study subgroup.

Characteristic	Glomerular Filtration Rate (ml/min)					p-Value
	≥ 90 (n = 1,927)	89–60 (n = 1,163)	59–30 (n = 841)	< 30 (n = 102)	Dialysis (n = 35)	
Preprocedural % diameter stenosis	84.9 ± 11.3	83.8 ± 11.2	83.9 ± 11.0	85.0 ± 11.7	81.6 ± 11.6	0.038
Postprocedural % diameter stenosis	0.8 ± 3.3	0.7 ± 2.5	0.8 ± 2.3	0.9 ± 2.6	1.0 ± 2.4	ns
Reference vessel diameter, mm	2.7 ± 0.6	2.7 ± 0.7	2.6 ± 0.6	2.5 ± 0.6	2.7 ± 0.7	< 0.001
Lesion length, mm	19.3 ± 10.1	18.6 ± 9.5	18.0 ± 10.0	17.8 ± 10.0	17.9 ± 8.5	0.012
Previously dilated lesion, n (%)	65 (3.4)	43 (3.7)	25 (3.0)	3 (2.9)	0	ns
Lesion in graft, n (%)	76 (3.9)	61 (5.2)	63 (7.5)	4 (3.9)	2 (5.7)	0.003
Total occlusion, n (%)	98 (5.1)	33 (2.8)	25 (3.0)	7 (6.9)	2 (5.7)	0.006
High-risk lesion*, n (%)	618 (32.1)	370 (31.8)	283 (33.7)	21 (20.6)	16 (45.7)	0.038

Unless otherwise specified, values indicate means ± SD.
P-value compares the distribution across the 5 renal function groups.
*According to the ACC/AHA classification.

causing a > 3.0 gm/dl decrease in blood hemoglobin content; and (b) vascular dissection or pseudoaneurysm documented by arteriography or ultrasound examination. The definitions of stent thrombosis developed by the Academic Research Consortium¹⁸ were applied.

Statistical analyses. Discrete variables are reported as frequencies (%), and continuous variables as mean ± standard deviation (SD). Chi-square tests of independence or exact tests, when appropriate, were used to compare discrete variables. Analysis of variance was used to compare continuous variables. The Kaplan-Meier method was used to produce actuarial survival estimates for death and MI, TVR and MACE. Overall and pair-wise log-rank testing was used to compare actuarial survivals among the renal function subgroups. For follow-up pair-wise comparisons of significant in-hospital outcomes, Bonferroni correction was used to adjust for multiple testing that yielded an $\alpha \leq 0.005$. Cox proportional hazards regression analyses were performed to examine the relationships between: (a) SES- versus PES-eluting stents; (b) multiple clinical variables; and (c) diabetes or anemia combined with level of renal function on the one hand, and (i) TVR, (ii) death, and (iii) MACE on the other hand. Hazard ratio (HR) and 95% confidence interval (CI) are presented. Results were considered statistically significant when $p < 0.05$.

Results

Baseline and procedural characteristics. The baseline and procedural characteristics of 2,758 consecutive DES recipients, subgrouped into 4 ranges of calculated GFR + 1 group of patients on long-term dialysis, are shown in Table 1. Patients with preserved renal function (> 60 ml/min) were more likely to be men, young, current smokers and treated with a GP IIb/IIIa inhibitor. Patients with impaired renal function (< 60 ml/min) were more likely to be women, hypertensive (data not shown), suffer from congestive heart failure and from peripheral or cerebral arterial disease, or

operated coronary artery disease. Hemodialysis was used in 91.3% and peritoneal dialysis in 8.7% of dialyzed patients. Information regarding the administration of angiotensin-converting enzyme inhibitor and angiotensin receptor-blocker was available in 2,527 (91.6%) of the overall patient population; one or both were given in 70.9% of the normal renal function patients, and in 64.8%, 72.1%, 59.3% and 76.2% of patients in each respective decremental group. The mean left ventricular ejection fraction was $51.7 \pm 10.9\%$ in the normal group, and was 52.4 ± 12.1 , 51.1 ± 13.1 , 48.6 ± 14.6 and $50.7 \pm 10.3\%$ in each respective decremental group.

Lesion characteristics. The baseline characteristics of the 4,068 lesions treated are shown in Table 2. The majority were *de novo* lesions in native coronary arteries. Overall, the mean reference vessel diameter was 2.7 ± 0.6 mm, and the mean lesion length was 18.8 ± 9.9 mm.

In-hospital outcomes. The rates of in-hospital adverse clinical events are shown in Table 3. While no patient undergoing long-term dialysis suffered an early adverse clinical event, the rates of death among patients with moderate or severe renal insufficiency (0.7% and 4.6%, respectively) were significantly higher than in patients with a GFR > 60 ml/min. The incidence of vascular bleeding complications, dissection or pseudoaneurysm was significantly higher among patients with severe renal insufficiency than in patients with normal renal function, despite the more prevalent use of GP IIb/IIIa inhibitors among patients with preserved renal function.

Long-term survival and adverse clinical events. At a mean follow up of 706 ± 273 days, information was available for 98.8% of patients.

Target vessel revascularization, death and myocardial infarction. The actuarial survivals free from: (a) TVR, (b) death and MI, and (c) MACE in each study subgroup are shown in Figures 1 A, B and C, respectively. While the difference in the event-free survival distributions of TVR over 2 years did not reach statistical significance, the p -value indicates a trend toward increased clinical need for revascularization

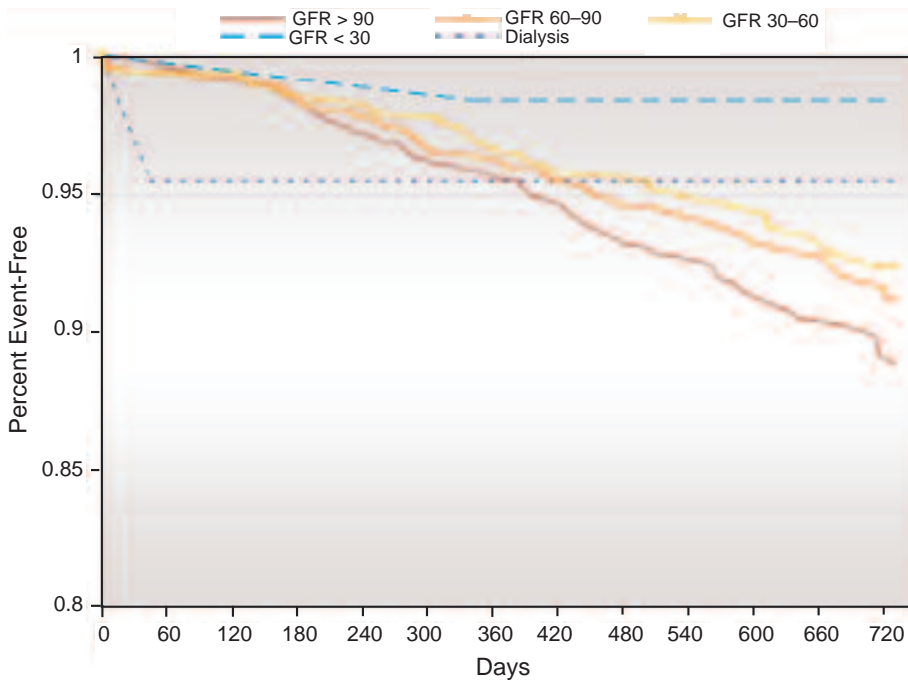


Figure 1A. Two-year actuarial survival free from target vessel revascularization of the study subgroups.

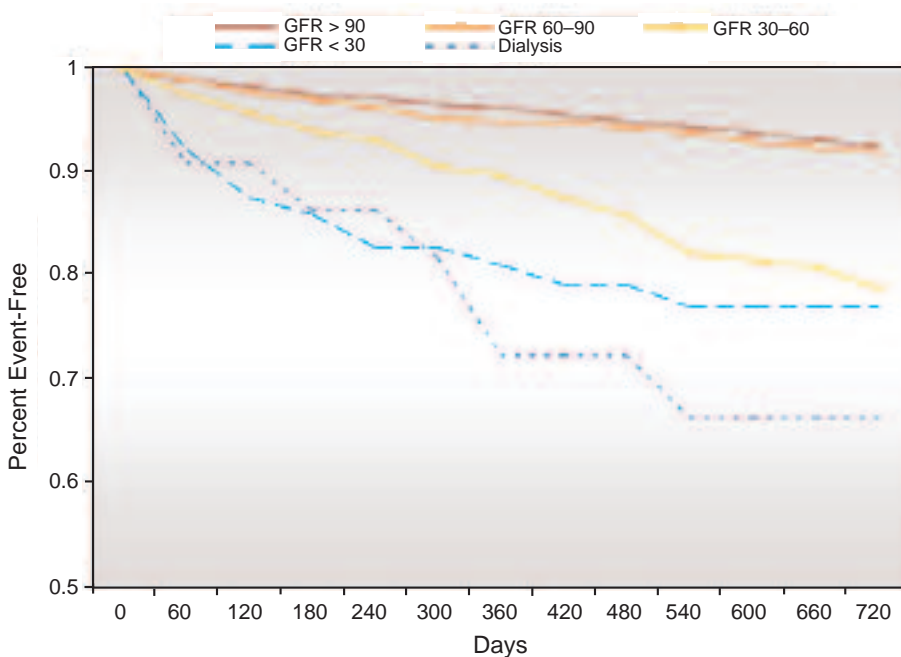


Figure 1B. Two-year actuarial survival free from death + myocardial infarction of the study subgroups.

among patients with preserved renal function ($p = 0.069$; Figure 1A). Patients with worse renal function were observed to have higher rates of death and MI ($p < 0.001$; Figure 1B) and MACE ($p < 0.001$; Figure 1C).

Normal renal function versus chronic renal disease. Patients with preserved renal function had significantly lower 1- and 2-year rates of death, death + MI and MACE than the patients suffering from chronic renal disease. A nonsignificant

trend was observed toward a lower incidence of 1- and 2-year rates of TVR in the GFR < 60 ml/min group.

Stent thrombosis. The incidence of early, late and very late, definite and probable stent thromboses in patients with GFR ≥ 60 ml/min versus GFR < 60 ml/min was similar (Table 5).

Sirolimus- versus paclitaxel-eluting stents. The 18-month survival free from TVR after implantation of SES- versus PES-eluting stents was similar, both in patients with a GFR ≥ 60 ($p = 0.254$) and patients with a GFR < 60 ml/min ($p = 0.380$) (Figure 2).

Predictors of adverse events. Multiple putative clinical predictors of TVR, death and MACE were entered into a regression analysis, including: age, gender, weight, GFR ≥ 60 versus < 60 ml/min, treatment with long-term dialysis, diabetes, anemia, hypertension, hypercholesterolemia, smoking status, type of DES implanted, use of GP IIb/IIIa inhibitor, family history of coronary artery disease, history of MI, coronary artery bypass surgery, congestive heart failure, cerebral vascular disease or peripheral vascular disease, interaction between renal dysfunction (GFR < 60 ml/min) and anemia, and interaction between renal dysfunction and diabetes. When adjusting for the aforementioned variables, a GFR < 60 ml/min independently remained a significant predictor of death (HR 1.65; 95% CI 1.21–2.24; $p < 0.001$) and MACE (HR 1.45; 95% CI 1.20–1.77; $p < 0.001$), but did not predict TVR. The interaction effects between renal dysfunction, anemia and diabetes were not significant.

Discussion

As is often the case in clinical trials of cardiovascular diseases,¹⁹ the pivotal trials which established the antirestenotic effects of DES specifically excluded or underrepresented patients with moderate-to-severe renal insufficiency. While previous studies from the pre-DES era have established increased rates of MACE and mortality among renally insufficient patients,²⁻⁵ studies to confirm these findings in the DES

era in unselected patient populations have been few. This analysis provides a detailed, contemporary description of the clinical outcomes after implantation of SES- or PES-eluting stents in a large, unselected population of patients with renal function ranging between normal and end-stage failure, with a very high compliance rate at 2-year clinical follow up.

Chronic renal disease and in-hospital outcomes. Patients with a GFR < 30 ml/min who were not on long-term dialysis were at highest risk of dying before their discharge from the hospital. This was not attributable to more complex coronary disease, since this subgroup had the lowest prevalence of high-risk lesions. We hypothesize that the poor general health and advanced mean age of these patients precluded their candidacy for dialysis. This subgroup also suffered

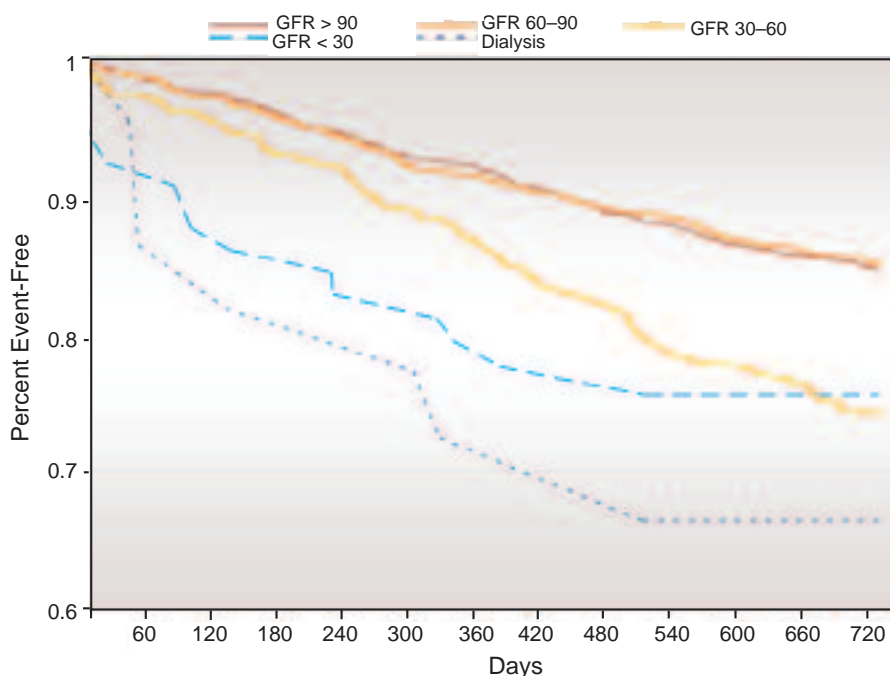


Figure 1C. Two-year actuarial survivals free from major adverse cardiac events of the study subgroups.

Table 3. In-hospital adverse clinical events.

Event	Glomerular Filtration Rate (ml/min)					p-Value
	≥ 90 (n = 1,316)	89–60 (n = 777)	59–30 (n = 577)	< 30 (n = 65)	Dialysis (n = 23)	
Death	6 (0.5) ^{ab}	0 ^a	4 (0.7) ^b	3 (4.6) ^c	0 ^{a,b,c}	0.006*
Periprocedural myocardial infarction	5 (0.4)	7 (0.9)	1 (0.2)	0	0	ns
Congestive heart failure	0	1 (0.1)	1 (0.2)	0	0	ns
Postprocedural renal failure	0 ^a	0 ^{ab}	4 (0.7) ^c	1 (1.5) ^{b,c}	0 ^{a,b,c}	0.047*
Emergency CABG	1 (0.1)	0	0	0	0	ns
Emergency PCI	1 (0.1)	0	0	0	0	ns
Cardiogenic shock	0	1 (0.1)	0	0	0	ns
Cerebrovascular accident	1 (0.1)	0	2 (0.3)	0	0	ns
Vascular complications	8 (0.6) ^a	11 (1.4) ^{ab}	9 (1.6) ^{ab}	3 (4.6) ^b	0 ^{ab}	0.016*

Values indicate number (%) of patients in corresponding group. P-value compares the distribution across the 5 renal function groups.

*Letters indicate which groups differ significantly from one another. Groups sharing a letter do not differ significantly.

CABG = coronary artery bypass graft surgery; PCI = percutaneous coronary intervention.

the highest incidence of procedure-related vascular complications, probably because of the increased hemorrhagic risk associated with severe renal insufficiency. Patients with a reduced GFR were also more likely to experience worsening renal function after exposure to contrast material during the PCI procedure. Finally, it is noteworthy that the overall incidence of clinically manifest stroke was very low.

Chronic renal disease and target vessel revascularization. In the TAXUS IV trial, recipients of PES with a GFR < 60 ml/min had a 1-year TVR rate of 6.6%, versus 8.0% with a GFR between 60 and 89 ml/min, and 6.9% with a GFR ≥ 90 ml/min.¹⁴ In a study from Rotterdam, the 1-year rate of TVR after implantation of SES was 7.2% in patients with a

GFR ≥ 60 ml/min, and 5.6% in patients with a GFR < 60 ml/min.¹⁵ Smaller registries have also confirmed the effectiveness of DES in reducing the need for TVR in patients with various degrees of renal insufficiency or on dialysis, though patient follow up were incomplete and limited to 1 year.^{13,20-23}

Our study, which extended the survival observations to 2 years in a much larger patient population, confirmed low overall rates of clinically-driven TVR in all subgroups, and a similar performance by both currently commercially available DES. While there was an apparent decrease in the rate of repeat PCI for TVR as renal function declined, the extremely low 1.6% revascularization rate observed in the group with severe renal insufficiency might have been due to fatal events

Table 4. One- and two-year Kaplan-Meier survival estimates in patients with a GFR > 60 ml/min versus a GFR < 60 ml/min.

	GFR ≥ 60 ml/min		GFR < 60 ml/min		p-Value
	1-Year	2-Year	1-Year	2-Year	
Death	97.5 (96.8–98.1)	95.3 (94.2–96.2)	90.3 (87.7–92.3)	82.3 (78.9–85.2)	< 0.001
Death and MI	95.7 (94.7–96.5)	92.2 (90.8–93.3)	88.6 (85.9–90.9)	78.4 (74.8–81.6)	< 0.001
TVR	95.8 (94.9–96.6)	89.7 (87.9–91.3)	96.8 (95.1–97.9)	92.9 (89.9–95.1)	0.057
MACE	91.7 (90.4–92.8)	84.7 (83.0–86.3)	85.7 (82.7–88.2)	74.4 (70.5–77.8)	< 0.001

Values indicate % event-free (95% confidence interval).
 P-values compare the overall 2-year survival distributions for a GFR ≥ 60 versus a GFR < 60 on each outcome.
 GFR = glomerular filtration rate; MI = myocardial infarction; TVR = target vessel revascularization; MACE = major adverse cardiac events.

Table 5. Numbers (%) of definite and probable stent thromboses* in patients with a GFR ≥ 60 ml/min versus a GFR < 60 ml/min.

	Glomerular Filtration Rate		p-Value
	≥ 60 ml/min (n = 2,093)	< 60 ml/min (n = 642)	
Stent thrombosis total	23 (1.10)	8 (1.25)	ns
Early (< 30 days)	6 (0.29)	5 (0.78)	ns
Late (30–365 days)	4 (0.19)	1 (0.16)	ns
Very late (> 365 days)	13 (0.62)	2 (0.31)	ns

Values indicate number (%) of patients in corresponding group.
 *Academic Research Consortium classification

preempting the development of restenosis, since the death rate in that group was 16.4%. This is supported by the negative predictive value of age with respect to TVR (older age was associated with a lower likelihood of TVR), such that patients with severe renal insufficiency did not survive long enough to develop restenosis. Other tentative explanations include a lower prevalence of diabetes among patients with severe renal insufficiency, or reluctance on the part of physicians to repeat PCI in gravely ill patients.

Chronic renal disease and stent thrombosis.

Recent observations have suggested that the incidence of late stent thrombosis might be higher among unselected patients who receive DES than in patients who were included in the pivotal randomized trials. While renal insufficiency has been suggested as a risk factor for the development of late and very late stent thrombosis,²⁴ we did not find a higher incidence of definite and probable, late and very late, stent thromboses in patients with severe renal dysfunction compared with patients with normal or mildly-to-moderately reduced renal function, although our study was underpowered to detect significant differences.

Chronic renal disease and mortality. Chronic renal and cardiovascular diseases are interrelated and have overlapping effects on health and survival. As kidney function declines, several adverse cardiovascular events might be exacerbated including volume overload, cardiac remodeling, derangements in calcium-phosphate metabolism, inflammation, hypertension and dyslipidemia.²⁵ Patients with both chronic renal and cardiovascular diseases are at 2- to 3-fold higher risk of death than patients with cardiovascular disease only.²⁶

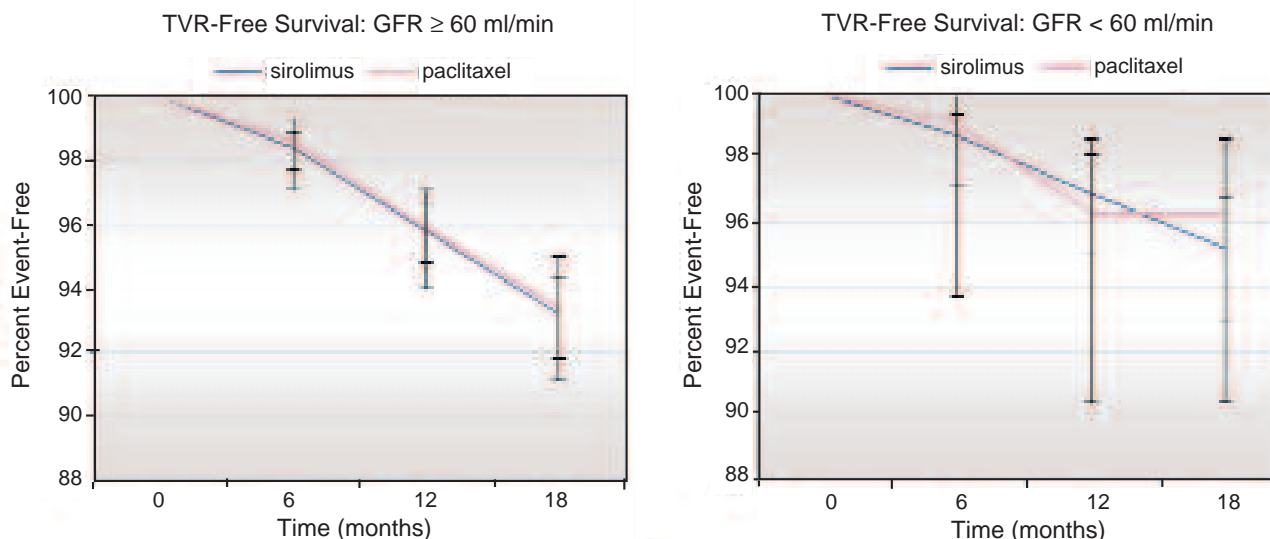


Figure 2. Actuarial survivals free from target vessel revascularization at 18 months in recipients of sirolimus- versus paclitaxel-eluting stents, grouped by a GFR ≥ 60 ml/min versus a GFR < 60 ml/min.

The complex interaction among various characteristics of renal failure and cardiovascular risk factors may generate a vicious cycle in which one promotes the progression of the other, a disorder known as “cardiorenal syndrome”.²⁸

In our study, the 2-year mortality rate ranged from a low of 4.0% in patients with normal renal function to 24.3% in the dialysis group, with a significant increase between patients with a GFR < 60 versus \geq 60 ml/min. In a recent analysis of the National Heart, Lung and Blood Institute Dynamic Registry, dialyzed patients undergoing DES had an 82.3% 1-year survival versus 62.7% after BMS implantation, a difference that was nearly statistically significant.²³ It is noteworthy that the 1-year survival rate of our patients on dialysis (81.6%) was nearly identical to that measured in that registry.

Study Limitations

This study was retrospective and observational, thus susceptible to biases introduced by unmeasured factors. Our definition of renal function relied on a single creatine measurement at the time of hospital presentation, and therefore may not have been representative of a stable clinical state. However, we used a validated equation to estimate GFR instead of an isolated serum creatine value. Data regarding the dosage and timing of preprocedural clopidogrel was not available. Postprocedural creatine, hemoglobin and cardiac enzyme measurements were not systematically available, potentially lowering the detection of adverse outcomes such as periprocedural MI and/or worsening of renal function caused by contrast material, bleeding or anemia. Finally, the number of patients with severe renal insufficiency/dialysis was relatively small, limiting the ability to detect significant differences in outcome measures between the groups.

Conclusions

In this analysis of the largest number of consecutive, unselected patients with various degrees of renal insufficiency, including patients on long-term dialysis, SES and PES appeared to be equally effective in preventing long-term TVR, regardless of the severity of renal dysfunction. We did not observe a relationship between renal dysfunction and risk of definite and/or probable stent thrombosis. A strong relationship was observed between decreasing GFR and increasing risk of death and MACE over 2 years.

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