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Embolic protection device use in renal artery stent placement

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Abstract

Purpose—The purpose of the present study was to report our experience with the safety, efficacy, and renal function outcomes using the GuardWire embolic protective device (EPD, Medtronic AVE, Minneapolis, MN) with renal artery stenting for patients with renal artery stenosis (RAS) and chronic renal insufficiency (CRI).

Methods and materials—This was a retrospective study of all patients with RAS with CRI who were treated with concomitant GuardWire EPD and renal artery stents from 12/2002 through 6/2006. Renal function was determined by calculating estimated glomerular filtration rate (eGFR) using Modification of Diet in Renal Disease formula, and subjects were divided into Kidney Disease Outcome and Quality Initiative (KDOQI) classes based on baseline eGFR. After revascularization, an improvement from baseline of 1 KDOQI class was defined as “improvement”, unchanged KDOQI class as “stabilization” and worsening of 1 KDOQI class as “deterioration”.

Results—There were 63 patients (Men=54%) with a mean age of 75.2 ± 7.7 years. The mean baseline serum creatinine and eGFR were 1.87 ± 0.6 mg/dL (1 – 3.8) and 36.63 ± 11.42 ml/min/ 1.73m^2 (13.85-59.99), respectively and at last clinical follow-up were 1.96 ± 0.72 mg/dL and 38.75 ± 13.25 mg/ml/ 1.73m^2 , respectively (P=NS). Over a mean follow-up period of 16 ± 12 months, 14 patients (25%) improved, 33 (58%) remained stable, and 10 (18%) deteriorated. There was one GuardWire related dissection which was successfully stented.

Conclusion—The GuardWire EPD used during renal artery stent placement is safe and associated with stabilization or improvement in kidney function in 83% of the patients with RAS and CRI.

INTRODUCTION

In the United States of America, the incidence of atherosclerotic renovascular disease in patients whose age is 65 years is 3.7/1000 (1). The clinical sequelae of this can be uncontrolled hypertension and worsening renal function. Atherosclerotic renovascular disease is increasingly being recognized as a cause of renal failure and dialysis dependency.

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It is estimated 12-18% of end stage renal disease patients have ischemic nephropathy caused by renal artery stenosis as their underlying etiology (2).

The technical advances in endovascular procedures for treating renal artery stenosis have not translated into major improvements in outcomes after renal artery revascularization (3, 4). One potential etiology is that atheroembolism which can occur when there is release of cholesterol and plaque fragments from the atherosclerotic renal artery or aorta during catheter manipulations (5-7). A recent study reported a 42% incidence of atheroembolic particles measuring 1-3 mm size during guide catheter manipulations in the peri-renal aorta prior to renal artery angioplasty and stenting (5-7). *Ex vivo* and *in vivo* studies on carotid (8, 9) and renal arteries have shown that atheroembolism occurs with every manipulation across the stenosis in particular, after dilating the stent after deployment (10).

The use of embolic protective devices has become the standard of care in percutaneous revascularization of stenotic aorto-coronary saphenous vein bypass grafts with several embolic protective devices having received Food and Drug Association approval for this indication (11-14). Recently, several studies have described the use of embolic protective devices during renal artery stent procedures to minimize atheroembolism (15: Hiramoto, 2005 #29, 16-22). The purpose of the present study was to report our experience with the safety, efficacy, and early outcomes of renal function using the GuardWire embolic protective device (Medtronic AVE, Minneapolis, MN) during percutaneous renal artery angioplasty and stenting in patients with atherosclerotic renal artery stenosis for chronic renal insufficiency.

METHODS AND MATERIALS

Patient selection

Our hospital does not require Institutional Review Board approval for retrospective chart reviews. Ninety two patients with renal artery stenosis underwent renal artery angioplasty with stent placement and concomitant use with GuardWire embolic protection device and the study was performed from December 2002 to June 2006. Baseline and follow-up data were obtained on outcomes of death, renal transplantation, and hemodialysis. The inclusion criteria of the study was patients who had chronic renal insufficiency (estimated baseline glomerular filtration rate (eGFR) ≥ 60 ml/min) with or without hypertension and flash pulmonary edema. The primary endpoints included death, revascularization, dialysis, or renal transplantation at time of follow-up obtained through our medical records ending in February 2007. Patients who were hemodialysis dependent at the time of intervention (n=3), with in-stent restenosis at baseline (n=3), eGFR >60 ml/min (n=16), and those with less than one month follow-up (n=7) were excluded and the study is comprised of 63 patients.

Definitions and endpoints—The severity of pre-interventional renal impairment was classified using the Kidney Disease Outcome and Quality Initiative (KDOQI) by estimating the glomerular filtration rate (eGFR) calculated using the Modification of Diet in Renal disease equation (MDRD): $eGFR = 186 \times \text{Serum creatinine}^{-1.154} \times \text{Age}^{-0.203} \times 0.742$ (Females) $\times 1.210$ (African Americans) (23). For the purposes of a more detailed analysis, we divided class 3 into 3A (eGFR 45-59 ml/min/1.73 m²) and 3B (eGFR 30-44 ml/min/m²) (24, 25).

Renal artery stenosis was defined as a diameter reduction of greater than 50% by visual estimate when compared to its immediate, distal non-dilated main renal arterial segment at the time of intervention as defined by the guidelines published by the Society of Interventional Radiology (26). Renal artery stenosis were defined as “ostial” if they were located within less or equal to 5-mm distance away from renal artery origin from the aorta

and defined as “non-ostial” if it was located more than 5-mm away from renal artery origin. “Technical success” of the stent procedure was defined as less than 30% residual stenosis by visual estimation after deployment. “Technical success” of the embolic protective device was defined as successful deployment of the device, retrieval of the device, and adequate filtration. This was reported as the number of successful embolic protective device deployments per number of total attempted embolic protective device deployments. “Partial protection” of the kidney was when the device was deployed in usually the primary branch of the renal artery. “Complete protection” of the kidney was defined as complete protection of the renal artery with the device being deployed in the main renal artery. All complications were recorded according to the guidelines published by the Society of Interventional Radiology (26).

Improvement in kidney function was defined as an increase by one KDOQI stage at last follow-up when compared to baseline kidney function immediately prior to stent placement. Stabilization in kidney function was defined as no change in KDOQI stage in kidney function at last follow-up when compared to baseline kidney function immediately prior to stent placement. Deterioration in kidney function was defined as a change in one KDOQI stage in kidney function at last follow-up by one stage or more when compared to baseline kidney function.

Solitary functioning kidney was defined as one of the following: 1) history of prior nephrectomy, 2) if the ultrasound demonstrated a kidney size of less than 7-cm, or 3) there was no nephrogram by angiography.

GuardWire device—The GuardWire device was the sole embolic protective device used for all patients and consists of 3 components: 1) the GuardWire temporary occlusion balloon mounted on a 0.014” hollow-tube angioplasty wire made of Nitinol alloy, 2) the EZ Flator inflation system, and 3) the Export aspiration catheter. The GuardWire has a distal radiopaque marker with an inflatable compliant elastometric balloon with a diameter of the balloon ranging between 3 to 6-mm. The size of the balloon was chosen based upon the diameter of the reference vessel diameter of the non diseased renal artery from the diagnostic renal angiogram. The balloon is inflated so that there is complete occlusion of blood flow into the kidney. The distal 3.5-cm length of the wire is floppy and shapeable and is available in lengths of 190-cm and 300-cm, thus permitting either monorail or over-the-wire techniques. The proximal end of the hypotube wire incorporates a Microseal device that maintains the elastometric balloon inflated. The 5.2-F Export aspiration catheter is placed over the GuardWire prior to distal balloon deflation to aspirate debris through the beveled side-hole. This catheter is tapered to the guidewire which helps decrease the risk of atheroembolism or stent dislodgment during its advancement into the renal artery.

Procedure—All patients were prehydrated with intravenous 0.9% normal saline and treated with 4 doses of oral 600-mg N-acetyl cysteine; two doses 12 hours pre and two doses after the procedure. All patients were given 325 mg of aspirin before the procedure. All procedures were performed under the supervision of a single operator and the predominant access was through the common femoral artery using the modified Seldinger technique; whereas the brachial access was used due to technical reasons in 13 (21%) patients. Intravenous unfractionated heparin at 50-100 IU/kg (n=10, 16%) or bivalirudin (n=52, 84%) (Angiomax, The Medicines Company, Parsippany, NJ) at 0.5 mg/kg bolus followed by 1.75 mg/kg/hr infusion was administered once sheath was secured.

Diagnostic renal angiogram was performed using a 4F internal mammary artery (IMA, Boston Scientific, Natick, MA) catheter carefully engaged in the target renal artery ostium. The lesion was traversed with the 0.014” GuardWire through the 4-F diagnostic catheter.

The diagnostic IMA was then exchanged out for a 6-F renal guiding catheter (Boston Scientific), predominately an IMA shape, telescoped through a 23-cm 6-F or 7-F access sheath (Boston Scientific). Care was taken to avoid engaging the target lesion with the guide catheter tip, which was deliberately left outside the renal artery ostia. The GuardWire balloon was inflated with contrast (25% dilution with heparinized saline) and complete occlusion of the target main renal artery by the balloon was confirmed with a contrast injection of 2-4 ml by hand. Pressure gradients were not routinely measured to minimize manipulations across the stenotic lesion. Stents were positioned so that to extend 1 to 2-mm into the aortic lumen while completely covering the lesion to be treated. After successful stent deployment, the static column of blood proximal to the temporary occlusion balloon was evacuated using the rapid exchange Export aspiration catheter (Medtronic AVE) and 40-mL of blood was aspirated. The GuardWire balloon was then deflated, and completion selective renal angiography was performed. Patients were monitored overnight, sent home the following day on dual anti-platelet therapy with Plavix (Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership, Bridgewater, NJ) 75 mg daily for 1-month and aspirin 325-mg daily, indefinitely. A manual brachial blood pressure and the number and type of blood pressure medications were recorded. Anti hypertensive medication were considered beta blockers or angiotensin-converting enzyme inhibitors. Medications which were being used for managing edema such as lasix were not included. Renal function was evaluated by serum BUN and creatinine.

Statistical Methods—JMP 6.0.0 software (SAS Institute Inc, Cary, NC) was used for all statistical analyses. Categorical variables were expressed as percentages, and continuous variables as mean $\pm$ 2 standard deviations.

RESULTS

There were 63 patients, 34 male (54%), 59 Caucasians (95%), with a mean age of 75.2 ± 7.7 years old who underwent 63 renal arterial angiograms with renal artery stent placement for 85 renal artery stenoses. The cardiovascular risk factors included hypertension in 95% (n=60), dyslipidemia in 92% (n=58), history of smoking in 82% (n=49), coronary artery disease in 47 patients (76%), and diabetes mellitus in 30% (n=19) (Table 1).

Treatment with renal artery stent placement

All renal artery stenosis were ostial in location. The technical success rate of renal artery stenting was 100% using a variety of balloon expandable stents. We used either Herculink (Abbott Vascular, Santa Clara, CA), Racer (Medtronic AVE, Minneapolis, MN), and Palmaz Blue (Cordis Endovascular Corporation, Miami, FLA) stents. All of the treated renal arteries had ostial lesions. Twenty-one (33%) patients had bilateral stenting (inclusive of 2 who had 3 renal arteries stented under embolic protective device protection), 15 (24%) patients had stenting of solitary functioning kidney and 27 (43%) had unilateral stenting (Table 2).

GuardWire depolyment

The GuardWire was the only embolic protective device used during all procedures. Typically, a 3-6-mm embolic protective device device was used. In 3 (4%) of 85 renal artery stenosis only partial protection of the kidney was performed. This occurred in two patients because the diameter of the main renal artery was larger than 6-mm and the embolic protective device was placed into the larger of the first order branch and in one patient the landing zone in the main renal artery was not adequate because of early branching.

Debris within the embolic protection devices

On visual inspection, debris was observed in the aspirated blood from 90% of the treated arteries, but no formal analysis of the debris was performed.

Kidney function

The mean baseline serum creatinine and eGFR were 1.87 ± 0.6 mg/dL (1–3.8) and 36.63 ± 11.42 ml/min/1.73 m² (13.85–59.99), respectively and at last clinical follow-up were 1.96 ± 0.72 mg/dL and 38.75 ± 13.25 mg/ml/1.73 m², respectively (P=NS) (Table 3). At baseline, there were 17 patients (27%) in class IIIA, 24 patients (38%) in class IIIB, 21 patients (33%) in class IV and 1 patient (2%) in class V. At follow-up, fourteen patients (25%) had improved, 33 patients (58%) remained stable, and 10 patients (18%) deteriorated. Over a mean follow-up period of 16 ± 12 months, 14 patients (25%) improved, 33 (58%) remained stable, and 10 (18%) deteriorated. No patients progressed to hemodialysis or renal transplantation over the study period. There was no difference in outcome based on unilateral or bilateral intervention. The mean follow-up duration of the study group was 15.93 ± 12.2 months.

Hypertensive response

The mean baseline systolic and diastolic blood pressures were 164 ± 25 and 78 ± 12 mm of Hg respectively (data available n= 34; 54%) and at one month following renal stenting were 152 ± 27 and 78 ± 12 mm of Hg (data available n= 25, 40%, P=0.02 for change in systolic blood pressure from baseline and P=NS for change in diastolic blood pressure). The mean number of blood pressure medications at baseline and at one month after stenting were 2.6 ± 1.07 (data available n=50; 79%) and 2.6 ± 1.06 (data available n=33; 52%), respectively (P=NS).

Contrast used

All procedures were performed using low or iso-osmolal non-ionic iodinated contrast.

Complications

There was 1 (1%) GuardWire balloon related renal artery dissection in 85 deployments which was successfully stented.

DISCUSSION

In this study, we demonstrated the safety, feasibility and improvement or stabilization in benefit of the GuardWire distal embolic protection device with renal artery stent placement for atherosclerotic renal artery stenosis in patients with chronic renal insufficiency. At follow-up, fourteen patients (25%) had improved renal function, 33 patients (58%) remained stable, and 10 patients (18%) had deteriorated. Notably none of our study patients required either hemodialysis or renal transplantation following renal artery stenting during the follow-up period.

Recently, interventionalists have embraced the currently available embolic protection devices during renal artery stent placement. Although the previous reported results have been encouraging, these studies were universally fraught with several limitations, including the lack of uniformity in: selection criteria, study endpoint definitions, proportion of patients with advanced renal failure, and distribution of interventions on bilateral/solitary functioning kidney kidneys. Owing to these important differences in study design and other technical details, it remains exceedingly difficult to draw any conclusions, which can be extrapolated to the general population at risk. In addition, it is also speculative to attribute the reported

renal functional benefit to the use of the embolic protection device alone since stent placement alone has been shown to improve renal function.

The current reporting standards for renal revascularization studies lack a uniform endpoint definition with respect to renal function (26). Some authors have reported renal function in terms of serum creatinine change from baseline, which is confounded by anthropometric and demographic variables such as age, diet, gender, race and skeletal muscle mass. In contrast, renal function represented by GFR to some extent invalidates these confounding variables. Moreover, the definitions of “improvement”, “stabilization” or “deterioration” of renal function following renal revascularization have similarly not been standardized. Published studies defined these terms as changes in absolute values of serum creatinine (e.g., >0.2 mg/dL increase from the baseline defined as “failure”). However, changes in the percentage, instead of the absolute value from baseline, for defining “success” or “failure” is ideal, since the percentage change method nullifies the effect of the denominator (i.e. the absolute value of the baseline renal function). The percentage change in renal function from baseline, and the reported time period of that change from baseline has also been reported in various ways in previous studies, making the comparison of results between studies, as well as with the current study, complicated and confusing. In this study, we used the universally accepted KDOQI renal functional classification for defining the baseline renal function and for defining “improvement”, “stabilization” and “deterioration” from the baseline in part because of recent work by Go et al which showed clearly a cardiovascular benefit of maintaining kidney function (24).

In a study by Henry *et al*, 56 patients (66 renal arteries) underwent renal artery stent placement for the treatment of refractory hypertension (15). The interventions were performed with embolic protection devices using either the GuardWire (n=39), or FilterWire (n=26, Boston Scientific), or the Angioguard filter system (n=1, Cordis Endovascular Corporation). Due to the limited available sizing of these individual devices, those renal arteries measuring >6mm (for the GuardWire) and >5.5mm diameters (for FilterWire devices), were excluded from the study. The authors reported a 100% technical success rate and there were no device related complications. At 6-months, (with 80% follow-up rate) all subjects experienced “stable” renal function. In spite of these excellent results, the notable features of this study were 68% of the patients had normal baseline renal function and refractory hypertension, rather than ischemic nephropathy as the indication for renal artery revascularization. Furthermore, the endpoint definition of success was simply based upon the change in serum creatinine value from the baseline, rather than eGFR.

The first study by Holden and Hill was a case-control study [n=57; median age=72 years (59-85)] which involved 37 cases with embolic protection device and 20 without embolic protection devices (18). All patients had chronic renal insufficiency as the indication for revascularization, with 70-75% of the study group having moderate to severe renal failure. The Angioguard filter system was the protection device used, and in all cases “Dotter dilatation” was performed prior to embolic protection device deployment. The renal functional outcomes were outstanding (success rate: 95% in those with embolic protection devices use and 80% in those without). Their second paper was a cohort study [n= 63, median age=70 years (54-86)] which was comprised exclusively of patients with moderate to severe renal failure and in whom 70% of whom patients were also hypertensive (19). Angioguard (88%) and FilterWire EZ (12%) were the protection devices used in this study. The reported success rate was 97% at 6-months with the vast majority (92%) of the patients having revascularization of renal artery stenosis involving either bilateral or solitary functioning kidneys. These particular subgroups were reported to be associated with superior renal functional outcome rates compared to those with unilateral renal artery revascularization (27, 28) thus limiting the observations of this study with a “selection bias”.

Edwards *et al* [$n=26$; age 71 years (48-84)] used GuardWire during renal revascularization for patients with CRI (baseline serum creatinine 1.9 ± 0.7 mg/dL) and refractory hypertension, and reported 100% technical success and renal functional benefit at 1-month (17). There are limitations of this study in that there were 3 patients who had angioplasty without stenting, and 7 (30%) had renal artery stenosis secondary to in-stent restenosis, with a presumed lower incidence of distal embolization potential. In addition, bilateral interventions were staged, with a minimum interval of 1-month between each side, which may partially account for their superior renal functional outcomes. Lastly, an unknown number of patients with renal artery diameters >6 mm were not excluded from the final analysis, in whom the efficacy of the GuardWire could not be used because of the currently available sizes. A recently published study showed that 50% of main renal arteries on right side and 59% on the left side were >6 mm in their largest diameter, which limits the potential use of GuardWire embolic protection devices in a significant proportion of patients (29).

A recent study was performed using either the SpiderRX (eV3, Minneapolis, MN) or FilterWire embolic protection devices while performing renal artery stent placement in 23 patients treated for 29 RAS with stage 3-5 chronic renal insufficiency (20). After stent placement, there was stabilization or improvement in kidney function in 96% of the patients with significant decrease in systolic blood pressure. In 35% of the renal artery stent placements performed using a SpiderRX device, debris was observed within the device after stent placement.

More recently, the RESIST Trial results were reported (21). One hundred patients at 7 centers were randomly assigned to an open-label embolic protection device, (AngioGuard, Cordis), or double-blind use of a platelet glycoprotein IIB/IIIa inhibitor, abciximab, in a 2×2 factorial design. The primary end point was absolute change in MDRD derived eGFR and percentage change from baseline to 30 days after renal artery stenting plus abciximab, filter-based embolic protection, or both. GFR decreased significantly ($P < 0.05$) in the stent alone ($-7 \pm 16 / -10 \pm 20$) stenting and embolic protection device ($-9 \pm 16 / -12 \pm 21$), and stent with abciximab alone ($-7 \pm 13 / -10 \pm 20$) groups, but did not decline in the group with stenting under combined embolic protection device with abciximab protection ($+2 \pm 14 / +9 \pm 30$). Abciximab reduced the occurrence of platelet-rich emboli in the filters from 42% to 7% ($P < 0.01$) but no difference was observed in the capture of atheromatous debris (21 vs. 19%; $P = \text{NS}$).

There are several possible explanations for the lack of benefit of embolic protection in this study. First, the study enrolled patients with a 50%-diameter reduction. Renal blood flow does not fall until the stenosis severity exceeds 70% and most authors would agree that a stenosis would have to be 70% or have a 10 mmHg mean or 20 mmHg peak systolic gradient to be clinically significant. More recently, renal fractional flow reserve and brain natriuretic peptide have been found to be better predictors of improved blood pressure response post renal artery stent placement (30, 31). Second, capture of atheromatous debris was low at 17-21% of cases, whereas most studies of renal artery stent placement with the GuardWire document much higher capture rates of 44-100% (15, 17); and in our study, it was approximately 90%. Third, the lower capture efficiency rate may be related to the considerable bulky crossing profile of the AngioGuard relative to the GuardWire-3.5F vs. 2.8F. Predilatation was permitted to facilitate the AngioGuard delivery, but the authors do not comment about how often this was necessary. It is well established in the coronary saphenous vein graft and carotid beds that pre-dilatation is associated with release of atheromatous particles, and that some of the potential benefit of embolic protection may have nullified due to pre-dilatation (10).

In the current study we tried to overcome many limitations of previous studies by careful design and application of rigorous selection criteria. Contrary to prior studies, patients with in-stent restenosis, which presumably have a lower risk of atheroembolization, were excluded from our study. This selection methodology gave our study the desired reduced freedom from bias due to several confounding factors, which could either positively or negatively influence the renal functional outcomes following revascularization.

We defined renal functional benefit in study patients as stable or improved based upon the baseline and follow-up KDOQI classes rather than renal functional tests such as serum creatinine or eGFR which are fraught with inter and intraobserver and daily variation from dietary content, hydration level and medications. Notably none of the study patients required either hemodialysis or transplantation over the study period. Larger multi-center case-control studies particularly involving advanced renal failure patients may strengthen our results.

There are several limitations to the current study. Due to its retrospective nature and the lack of control group, our report is associated with all the inherent limitations of its design. Since the study sample is a referred population to a tertiary care center, the results are subjected to “selection bias”, which limits the power of our observations. A formal analysis of aspirate was not performed, however we observed visible debris in majority (around 90%) of study patients. Lastly, as we did not routinely image index renal artery patency during follow-up, we cannot exclude restenosis, rather than atheroembolism, as a possible cause for post-revascularization renal functional deterioration.

In conclusion, GuardWire distal embolic protection device is safe and feasible in stent-supported renal angioplasty for symptomatic atherosclerotic renal artery stenosis. Renal artery stent placement under GuardWire protection is associated with stabilization or improvement in 83% of the patients as measured by eGFR in advanced renal failure (KDOQI classes 3, 4 & 5). Larger, prospective, multi-center case-control studies are needed to substantiate and support our results and also identify the role of embolic protection in early renal failure patients. Finally, currently available GuardWire balloon sizing is not designed for arteries with a diameter of >6mm, may migrate when inflated in larger vessels, and is unsuitable for renal arteries with a lesion to distal bifurcation length of < 2 cm. Hence, a dedicated embolic protection device designed with these renovascular anatomical features taken into account may further improve its efficacy during percutaneous renal artery therapeutic interventions.

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Table 1

Baseline demographic and clinical characteristics

	<i>n</i> (%)	Data available (<i>n</i> =)
<i>n</i> =	63	
Men	34 (54)	63
Caucasians	59 (95)	62
Mean age intervention (years)	75.2 ± 7.7	63
Hypertension	60 (95)	63
Diabetes mellitus	19 (30)	63
Dyslipidemia	58 (92)	63
Tobacco abuse	49 (82)	63
Coronary artery disease	47 (76)	63
# Baseline anti-hypertensive medications	2.6 ± 1.1	50

Table 2

Angiographic variables

	<i>n</i> (%)	Data available <i>n</i> =
Anticoagulant used		62
Bivalirudin	52 (84)	
Un-fractionated heparin	10 (16)	
Ostial	63 (100)	63
Unilateral interventions	27 (43)	63
Interventions on bilateral renals/solitary functioning kidneys	36 (57)	63
Procedural complications	1(27)*	63

* GuardWire balloon related renal artery dissection, which were successfully stented

Table 3

Renal function data:

	Baseline n= (%)	*Last f/u n= (%)
Data available	63	57 (91)
Serum creatinine (mg/dL)	1.87 ± 0.6	1.96 ± 0.72
eGFR (ml/min/1.73 m ² BSA)	36.63 ± 11.42	38.75 ± 13.25
KDOQI class		
3A	17 (27)	13 (23)
3B	24 (38)	23 (40)
4	21 (33)	20 (35)
5	1 (27)	0 (27)
Improved	N/A	14 (25)
Stable	N/A	33 (58)
Deteriorated	N/A	10 (18)
Hemodialysis	None	None
All-cause deaths	N/A	9 (14)

* Follow-up duration: 16 ± 12 months