Published in final edited form as:

Catheter Cardiovasc Interv. 2010 November 15; 76(6): 795–801. doi:10.1002/ccd.22656.

Coronary Angiography is a Better Predictor of Mortality than Non-Invasive Testing in Patients Evaluated for Renal Transplantation

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Abstract

Objectives—The goal of this study was to compare whether coronary angiography or noninvasive imaging more accurately identifies coronary arter disease (CAD) and predicts mortality in patients with end-stage renal disease (ESRD) under evaluation for transplantation.

Background—CAD is a leading cause of mortality in patients with ESRD. The optimal method for identifying CAD in ESRD patients evaluated for transplantation remains controversial with a paucity of prognostic data currently available comparing noninvasive methods to coronary angiography.

Methods—The study cohort consisted of 57 patients undergoing both coronary angiography and stress perfusion imaging. Severe CAD was defined by angiography as $\geq 70\%$ stenosis, and by non-invasive testing as ischemia in ≥ 1 zone. Follow-up for all cause mortality was 3.3 years.

Results—On noninvasive imaging, 63% had ischemia. On angiography, 40% had at least one vessel with severe stenoses. Abnormal perfusion was observed in 56% of patients without severe disease angiographically. Non-invasive imaging had poor specificity (24%) and poor positive predictive value (43%) for identifying severe disease. Angiography but not non-invasive imaging predicted survival; three year survival was 50% and 73% for patients with and without severe CAD by angiography ($p < 0.05$).

Conclusions—False positive scintigrams limited non-invasive imaging in patients with ESRD. Angiography was a better predictor of mortality compared to non-invasive testing.

Index words

Angiography; Prognosis; Atherosclerosis; Renal Failure

INTRODUCTION

Chronic kidney disease, particularly end stage renal disease (ESRD) treated with hemodialysis, is a powerful, independent risk factor for coronary artery disease (CAD) (1,2). In addition, traditional risk factors such as hypertension, diabetes and hyperlipidemia are common coexisting conditions. This highly atherogenic milieu in patients with ESRD results in a CAD associated mortality 10–20 times greater than the normal population (3).

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Financial Disclosures: None

Patients with ESRD under consideration for renal transplantation represent a particularly challenging population as coronary disease remains a leading cause of mortality limiting the long term success of renal transplantation (4). Pre-transplant screening could help identify individuals that may require more aggressive evaluation and therapy, but the optimal method for screening these patients remains controversial. The clinical utility of non-invasive modalities including SPECT perfusion imaging and dobutamine echocardiography have been limited by a low sensitivity and specificity in this subgroup (5–12) and, although coronary angiography accurately identifies luminal obstruction from coronary disease (3,13,14), it is an invasive test and poorly suited for serial assessments in patients likely to remain on a waiting list for several years before transplant.

Pre-transplant screening for coronary disease is not just about estimating peri-operative risk; a more valuable purpose lies in its ability to predict long-term mortality. Given the limited donor pool and the tremendous resource utilization, renal transplantation offers little benefit to individuals not expected to survive at least 3 years. There are little data comparing coronary angiography to non-invasive imaging in an unselected cohort of ESRD patients under evaluation for renal transplant to not only determine which modality best identifies CAD but also to examine which modality better predicts long-term survival. Thus, the goal of this study was both to determine the ability of non-invasive techniques to identify significant CAD seen on angiography and to determine which modality more accurately predicts long-term mortality.

METHODS

Patient Population

Based on the American Society of Transplantation's guidelines, we developed an algorithm to guide the cardiac evaluation of patients prior to renal transplantation (Table 1) (15). In general, for patients initially evaluated with non-invasive testing, our institution prefers dipyridamole or adenosine sestamibi perfusion scintigraphy; coronary angiography is recommended in "high-risk" patients and in "intermediate" risk patients with significant ischemia on a non-invasive test.

Between January 1, 1999 and December 31, 2006, 253 consecutive ESRD patients underwent coronary angiography as part of their pre-transplant evaluation; 224 were classified as "high risk" and 29 were "intermediate" risk with ischemia on a stress test. Among the 224 "high risk" patients, 28 also had a non-invasive evaluation prior to the angiogram and thus, the study cohort consisted of 57 patients who had both a non-invasive evaluation and a coronary angiogram as a prelude to renal transplantation.

Clinical variables including patient demographics, risk factors, comorbidity, cardiac symptoms, and laboratory results were prospectively collected prior to catheterization according to definitions established by the American College of Cardiology- National Cardiovascular Data Registry (ACC-NCDR) guidelines and entered into point-of-care databases (CAOS [IBS Inc., Winston-Salem, NC] from January 1999 through December 2005, and Encompass™ [Agfa Heartlab Inc., Greenville, SC] from January 2006 through December 2006).

Coronary Angiography

Coronary angiography was performed by standard techniques and images interpreted by experienced cardiologists blinded to the results of the non-invasive tests. Multiple angiographic projections were obtained. The attending cardiologist performing the procedure entered the angiographic and procedural findings from the catheterization procedure into the database at the time of the procedure using the rigorous data definitions

provided by the ACC-NCDR. For the purposes of this analysis, patients were considered to have significant CAD if at least a 50% stenosis was present and severe CAD if at least a 70% stenosis was present in the proximal or mid segments of one of the three major epicardial coronary arteries (right coronary, left circumflex or left anterior descending artery) or in the proximal portion of one of their major branches (ramus intermedius, first or second obtuse marginals or first diagonal artery). For patients with prior bypass surgery, each vessel was classified relative to the bypass graft supplying it; thus, if the native artery had severe disease proximal to the anastomosis but the bypass graft was patent without obstructive disease and there was no obstructive disease distal to the anastomosis, then the artery was classified as showing non-significant CAD.

Non-invasive Stress Testing Protocols and Image Analysis

Patients refrained from taking methylxanthine containing medications for 24 hours before the test, and had no caffeine, food or beverages for at least 6 hours. One hour after the intravenous injection of 10 mCi ^{99m}Tc -sestamibi, patients underwent the rest imaging portion of the stress test. Prior to starting the stress portion of the test, a baseline 12 lead ECG as well as heart rate and blood pressure in the supine and standing position were obtained. During stress testing, patients underwent continuous ECG monitoring and recordings of blood pressure, heart rate, and 12 lead ECG made every minute for 12 minutes or until any abnormalities returned to baseline.

For patients able to exercise ($n = 5/57$ or 9%), stress testing was accomplished using the Bruce, Naughton or Balke protocols with the goal of achieving at least 85% or greater of maximum age-predicted heart rate (achieved in all 5 exercising patients). Radiotracer injection (30 mCi ^{99m}Tc -sestamibi) occurred at the point of maximal stress. For patients unable to exercise, pharmacologic stress was induced with either adenosine ($n = 6$) (continuous infusion of $140\mu\text{g/kg/min}$ over 4 minutes) or with dipyridamole ($n = 46$) (0.57 mg/kg/min IV push over 4 minutes). If possible, the patient walked on a treadmill at a slow pace at zero grade. Administration of 30 mCi ^{99m}Tc -sestamibi occurred 3 minutes into the adenosine infusion and 3 minutes after the dipyridamole infusion was completed. The SPECT perfusion images were obtained 30–60 minutes after injection. Image analysis was accomplished using computer assisted algorithms as previously described (16). Scintigrams were divided into 17 segments and images interpreted both visually and quantitatively by an attending cardiologist blinded to the results of the cardiac catheterization. Abnormal perfusion was defined for a segment if radiotracer uptake was $< 75\%$ of a normal reference segment and ischemia was present if uptake increased by at least 5% between the stress and rest images.

Follow-Up and Study End Points

Patients were followed for a median of 3.3 years (mean 3.5 years). The primary end point was all-cause mortality. Death was determined by review of the Renal Transplant Database, the University of Virginia's clinical database, and the Social Security Death Index (17).

Statistical Analysis

Descriptive data are expressed as absolute numbers and percentages of patients or findings. Age is expressed as a mean and dialysis time as a median and 25th, 75th percentile. The correlation between ischemia on noninvasive imaging and severe stenosis ($>70\%$) on cardiac catheterization was determined using Kendall's tau correlation coefficient. Mortality, as predicted by ischemia or severe stenosis on catheterization, is expressed using Kaplan-Meier survival curves with p-values determined using log-rank tests. All statistics were performed with SAS 9.1.3.

RESULTS

Clinical Characteristics (Table 2)

The study cohort of 57 patients with both invasive and non-invasive studies consisted primarily of patients over 50 years old with a high prevalence of traditional risk factors for coronary disease. Diabetes was present in 61% and nearly all patients had hypertension and dyslipidemia. Although 42% of patients had known coronary disease, (defined as prior myocardial infarction, revascularization procedure or coronary disease identified on previous catheterization), the majority were asymptomatic with only 17.5% of patients reporting angina. Despite the high prevalence of associated risk factors, only 58% were treated with aspirin or clopidogrel and only 61% of patients were treated with statins. Nearly all patients (93%) were on hemodialysis; 4 patients with advanced renal failure were not yet on dialysis at the time of catheterization. Renal transplantation was accomplished in 29 patients after coronary angiography; no patient was denied transplantation based on the results of coronary angiography.

Non-invasive Testing (Table 3)

Ventricular function was either normal or mildly reduced in the majority of patients; only 9 (16%) patients had ejection fraction less than 40%. Myocardial perfusion was entirely normal in 11(19%) patients. Among the 46 patients with abnormalities, 10 (17.5%) patients had only fixed defects involving at least one segment and 36 (63%) had reversible ischemia with or without additional fixed defects. Defects involved a single, definable vascular territory in 37 (65%) patients and two or more vascular territories in the remaining 9 patients.

Coronary Angiography

In 23 (40%) patients, coronary angiography revealed either angiographically normal arteries or no significant CAD. Among the 34 (60%) patients with significant CAD, 23 (40% of cohort) had severe disease (i.e., >70% narrowing); 10 of these involved a single vessel and 13 involved 2 or more vessels. Severe coronary disease affected the left anterior descending artery in 9 patients, the right coronary artery in 13 patients and the circumflex or ramus in 18 patients. No patient in this cohort had severe left main coronary stenosis. Five patients with symptoms or significant ischemia on non-invasive testing underwent revascularization after the catheterization; 4 were accomplished percutaneously and 1 with coronary bypass surgery. The remaining 18 patients with severe narrowing were asymptomatic and without significant ischemia on non-invasive testing and were treated medically.

Relationship Between Non-Invasive Testing and Coronary Angiography (Table 4)

Non-invasive imaging related poorly to the findings on coronary angiography. In this study, stress imaging had an unacceptably high rate of false positives. As shown in Table 4, any perfusion defect (either fixed or reversible) was present in 26/34 (76%) patients without severe coronary disease on angiography. When patients with fixed defects were excluded, the results were similar with ischemia present in 19/34 (56%) patients without severe coronary disease on angiography. The rate of false negatives was low with only 3/23 (13%) patients demonstrating normal perfusion despite severe coronary disease. Similar results were observed when comparing the relationship between non-invasive testing and coronary lesions of >50% in severity. Thus, the sensitivity, specificity, positive predictive value and negative predictive value of stress perfusion imaging for the detection of severe (>70%) stenosis on coronary angiography was 87%, 24%, 43% and 73% respectively. Furthermore, correlation between coronary angiography and non-invasive testing for identifying significant CAD was poor with a (Kendall's tau = 0.17).

Prognostic Value of Coronary Angiography vs Non-Invasive Imaging

For the entire cohort, the 1 and 3 year survival was 89% and 69%, respectively (Figure 1). Non-invasive testing did not provide prognostic information regarding survival as the survival curves for patients with and without ischemia on non-invasive testing were not different (log rank p value = 0.63, Figure 2). In contrast, coronary angiography discriminated survivors from non-survivors (log rank p value < 0.05, Figure 3). As shown in Figure 3, the one and 3 year survival for patients with severe (>70%) stenosis on coronary angiography was 72% and 50% compared to 91% and 73% for patients without severe coronary disease on coronary angiography.

DISCUSSION

Renal transplantation improves both survival and quality of life in patients with ESRD. However, due to both the intense utilization of resources and the limited availability of donors, it is important to offer this therapy to individuals most likely to accrue long-term benefit. Given the high prevalence of CAD and the increased incidence of cardiac mortality in these patients, it is natural that physicians focus on identification of patients at greatest risk of a cardiac event prior to transplantation. In addition to potentially excluding the highest risk individuals (18), this strategy might also allow more aggressive treatment of coronary disease, thereby reducing future cardiovascular events.

The goal of the present study was to evaluate the diagnostic accuracy of commonly used non-invasive tests for detecting severe coronary artery disease and to determine whether the findings on coronary angiography or non-invasive testing better predict long-term mortality in an intermediate to high risk cohort of patients with ESRD. We found that non-invasive tests, predominantly consisting of dipyridamole SPECT imaging, had a very poor specificity and positive predictive value for identifying severe (>70%) coronary disease. The sensitivity (87%) and negative predictive value (73%) of non-invasive testing was better, but a negative test would still leave a physician with substantial doubt. More importantly, this study found coronary angiography was better than non-invasive imaging at predicting subsequent mortality. The demonstration of ischemia on a non-invasive test offered no discriminatory value for predicting subsequent mortality. In contrast, identifying severe coronary artery disease on angiography distinguished those with worse survival.

Previous studies have compared non-invasive imaging to coronary angiography in patients with end-stage renal disease under evaluation for renal transplantation (9,14). Conflicting data is present in the literature and there remains significant controversy regarding the best screening approach. Differences in defining “high” versus “intermediate” risk patients and differences in the proportion of these risk categories likely explains some of the observed discrepancies. Despite this controversy, non-invasive testing remains one of the main tools in the pre-transplant evaluation at many institutions (15). Although it may not be necessary to perform cardiac catheterization on all intermediate risk patients, our observation regarding the high rate of false positive studies in these patients would inevitably lead to many coronary angiograms. Thus, the coronary angiogram, with its more definitive diagnostic and prognostic abilities, may, in fact, be a more efficient and cost-effective strategy than non-invasive testing for patients who are appropriate candidates for both studies. Coronary CT angiography might be a better non-invasive alternative, however, the high association of coronary calcification in renal failure patients and the relatively large contrast volume in individuals not yet on dialysis would limit its value.

It is not clear why there is such a high rate of false positive tests in this cohort. It is possible that these patients had diffuse microvascular disease not appreciated on the coronary angiogram and, in fact, truly had myocardial ischemia without epicardial stenoses. Our

institution has previously demonstrated marked abnormalities in coronary flow reserve in patients with ESRD and angiographically “normal” coronary arteries (19). This explanation may be irrelevant given the failure of ischemia on non-invasive imaging to subsequently predict mortality.

Limitations

The clinical algorithm used to evaluate patients prior to renal transplant in this study was created by consensus at our institution based upon clinical experience and published literature but has not been validated and this algorithm may have created a selection bias, thus influencing the results. We do not know the prevalence of severe CAD or subsequent mortality in the intermediate risk patients with a normal non-invasive study. However, the low rate of false negatives in the study cohort suggests that it is unlikely that patients with significant CAD are present in that group. In addition, we did not know the exact cause of death nor were we able to discriminate cardiac from non-cardiac etiologies and it is possible that causes of death other than cardiac ones accounted for these results. In addition, we did not have accurate data on the frequency of non-fatal cardiac events such as acute myocardial infarction in this cohort, and cannot comment on the ability of these modalities at predicting softer endpoints. Finally, in this relatively small cohort, we were not able to determine if other clinical variables are more important than coronary angiography at predicting outcomes in these complex patients such the influence of revascularization or transplant status. It is unlikely that revascularization would significantly impact mortality as large trials have shown no reduction in rates of death or myocardial infarction in stable CAD patients undergoing revascularization compared to optimal medical therapy (20).

Clinical Implications

While it is known that transplantation conveys a survival benefit to ESRD patients, recent data from our institution suggests that transplantation is associated with better survival regardless of the severity or extent of CAD (21). Thus, some may argue that defining coronary disease prior to transplantation is unnecessary. However, the identification of significant disease on angiography should lead to changes in therapy including aggressive and optimal medical therapy and revascularization where appropriate. These important steps can help reduce the rate of infarction and cardiac death in the post-transplant years.

It is interesting to note that, in the current cohort at very high risk of atherosclerosis, less than 60% of patients were on appropriate medical therapy. This represents an important and unexpected finding of this study. Before considering expensive and complex diagnostic or therapeutic strategies for these patients, physicians should place greater emphasis on implementing the well-known simple steps proven to benefit cardiovascular outcomes. This observation clearly represents a target for quality improvement and all transplant centers should focus on ensuring their patients are treated with optimal medical therapy. Coronary angiography, with its greater ability at identifying the presence of coronary disease, can help convince patients and physicians the importance of these therapies.

In conclusion, patients with ESRD under evaluation for renal transplantation at intermediate or high risk for coronary disease have a high prevalence of significant and often severe coronary artery disease. Non-invasive imaging has an unacceptably high rate of false positives and fails to provide prognostic information. Coronary angiography is the best predictor of subsequent mortality. Further studies are necessary to define the optimal screening strategy for this interesting and high risk patient cohort.

ABBREVIATIONS

ESRD	End-Stage Renal Disease
CAD	Coronary Artery Disease

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FIGURE 1.
Survival free from all cause mortality for the entire cohort.

FIGURE 2.

Comparison of survival free from all cause mortality for patients with and without ischemia on a non-invasive study.

FIGURE 3. Comparison of survival free from all cause mortality for patients with and without severe coronary disease (>70% stenosis) on coronary angiography.

TABLE 1

University of Virginia Algorithm for the Cardiac Evaluation of Patients with End-Stage Renal Disease Undergoing Evaluation for Renal Transplantation

RISK STATUS	CRITERIA	RECOMMENDATION
LOW	Age < 50 years and a normal ECG and no diabetes and no past history or symptoms of coronary artery, peripheral artery or cerebrovascular disease.	No further cardiac work-up before transplantation
INTERMEDIATE	Non-diabetic patients age > 50 years with no major coronary disease risk factors (dyslipidemia, family history, tobacco abuse) or no prior history of myocardial infarction or revascularization event, stroke or peripheral vascular disease Diabetic patient < 50 years but with duration of diabetes > 20 years and no other evidence of atherosclerosis	Exercise or pharmacologic stress test. If normal, no further work-up. If significant ischemia or reduced left ventricular function, then coronary angiography.
HIGH	Any patient with symptoms of angina, heart failure or prior cardiac event (myocardial infarction or revascularization), prior stroke or documented extra-cardiac atherosclerosis. Diabetes and any one of the following: age > 50 years, < 20 years duration of diabetes, history of smoking or dyslipidemia or an abnormal electrocardiogram suggesting prior, silent infarction.	Coronary angiography

TABLE 2**PATIENT CHARACTERISTICS**

N	57
AGE (YEARS)	54 ± 9
MALE	30 (53%)
TREATED DIABETES	35 (61%)
HYPERTENSION	55 (96%)
DYSLIPIDEMIA	49 (86%)
PRIOR OR CURRENT TOBACCO	33 (58%)
PRIOR PERCUTANEOUS CORONARY INTERVENTION	7 (12%)
PRIOR BYPASS SURGERY	4 (7%)
KNOWN CORONARY DISEASE	24 (42%)
PRIOR HEART FAILURE	13 (23%)
PERIPHERAL VASCULAR DISEASE	11 (19%)
CEREBROVASCULAR DISEASE	9 (16%)
ANGINA	10 (17.5%)
MEDICATIONS	
ASPIRIN/CLOPIDOGREL	33 (58%)
BETA BLOCKER	33 (58%)
ACE INHIBITOR/ARB	26 (46%)
STATIN	35 (61%)
DIALYSIS	53 (93%)
TIME ON DIALYSIS (DAYS)	1214 (447, 1930)

TABLE 3**FINDINGS ON NON-INVASIVE TESTING**

EJECTION FRACTION	52 ± 10%
EJECTION FRACTION < 40%	9 (16%)
NO DEFECT	11 (19%)
ANY DEFECT	46 (81 %)
FIXED DEFECT ONLY	10 (17.5%)
REVERSIBLE +/- FIXED DEFECT	36 (63%)
SINGLE VASCULAR TERRITORY	37 (65%)
MULTIPLE VASCULAR TERRITORIES	9 (16%)
LOCATION OF ABNORMALITY	
ANTERIOR	15 (26%)
LATERAL	6 (11%)
INFERIOR	35 (61 %)

TABLE 4
RELATIONSHIP BETWEEN NON-INVASIVE FINDINGS AND CORONARY ANGIOGRAPHY

	NO DEFECT	FIXED	ISCHEMIA
	(n = 11)	(n = 10)	(n = 36)
No Significant CAD* (n=23)	4	6	13
No Severe CAD (<70%) (n =34)	8	7	19
CAD >50% (n=34)	7	4	23
Severe CAD (>70%) (n=23)	3	3	17

* includes those with patent grafts (n =2)