Mild Renal Failure Is Associated With Adverse Outcome After Cardiac Valve Surgery

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• The present study was performed to ascertain whether the presence of mild renal failure (defined as a serum creatinine concentration of 1.5 to 3.0 mg/dL) is an independent risk factor for adverse outcome after cardiac valve surgery. An extensive set of preoperative and postoperative data was collected in 834 prospectively evaluated patients undergoing cardiac valve surgery at 14 Veterans Affairs Medical Centers. Univariate and multivariable analyses were performed to determine whether an independent association of mild renal dysfunction with adverse outcomes was present. Patients with mild renal failure had significantly greater 30-day mortality rates ($P = 0.001$; 16% versus 6%) and frequency of postoperative bleeding ($P = 0.023$; 16% versus 8%), respiratory complications ($P = 0.02$, 29% versus 16%), and cardiac complications ($P = 0.002$; 18% versus 7%) than patients with normal renal function (serum creatinine $<$1.5 mg/dL) when controlling for multiple other variables. The presence of a serum creatinine concentration of 1.5 to 3.0 mg/dL is significantly and independently associated with adverse outcomes after cardiac valve surgery.

INDEX WORDS: Renal failure; surgical outcomes.

MORE THAN 600,000 cardiac surgical procedures are performed annually within the United States. Delineation of risk factors for adverse outcome in patients undergoing cardiac surgery is of considerable potential value. For example, if modifiable risk factors are present, then individualized preoperative management could potentially improve outcome. Also, preoperative risk stratification not only allows for improved informed consent, but also can result in improved assessment of quality of care by the development of risk-adjusted outcome models.[1]

Most of the models developed to assess risk for adverse outcome after cardiac surgery focus on such variables as priority of surgery, previous cardiac surgery, cardiopulmonary functional status, and associated comorbid conditions.[2-23] Among the comorbid conditions frequently present in patients undergoing cardiac surgery are heart failure, hypertension, vascular disease, diabetes mellitus, and advanced age. These conditions are often associated with some degree of renal insufficiency.[12] Physiological abnormalities resulting from renal insufficiency could contribute to adverse outcome after cardiac surgery. Although it is clear that severe renal failure is associated with poor outcome after cardiac surgery,[24-30] there is limited information on the impact of mild renal failure on cardiac surgical outcome.[2,4,6,12,13]

Recently, using multivariable analyses, we found that an elevated preoperative serum creatinine concentration (median, 1.7 mg/dL) was significantly associated with adverse outcome after coronary artery bypass grafting (CABG) independent of multiple other variables.[31] The present analysis was performed to further test our hypothesis that mild renal insufficiency is an independent risk factor for adverse outcome after cardiac valve surgery. To extend our testing of this hypothesis, we selected a surgical population with a significantly greater mortality than for CABG. Specifically, we analyzed a prospectively obtained Veterans Affairs (VA) database containing an extensive set of preoperative and postoperative variables in more than 800 patients undergo-

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ing cardiac valve surgery, some of whom concomitantly underwent CABG.

METHODS

Data used for this study were extracted from VA Cooperative Study no. 5, Processes, Structures, and Outcomes of Care in Cardiac Surgery. Patients were entered onto this study from September 8, 1992, through December 31, 1996, from 14 of 43 VA hospitals with cardiac surgical programs. The VA hospitals were chosen to represent a spectrum of hospitals across the distribution of risk-adjusted 30-day mortality from cardiac surgery, as well as hospitals representative of VA facilities east and west of the Mississippi River.

A total of 4,969 patients were entered onto the study; 427 patients underwent cardiac valve surgery without an additional cardiac surgical procedure and 407 patients underwent cardiac valve surgery along with CABG. Data obtained from these 834 cardiac valve surgical patients, who had at least one baseline serum creatinine determination performed within 2 weeks of surgery, form the basis of this report.

Before data analysis, we categorized patients by three levels of baseline serum creatinine concentration. We divided patients into clinically relevant categories of serum creatinine levels less than 1.5 mg/dL (a normal value for most hospital laboratories), 1.5 to 3.0 mg/dL (a value considered by many to be mild to moderate renal failure, usually asymptomatic), and greater than 3.0 mg/dL (considered indicative of more advanced renal failure[32,33]). No data on creatinine clearance were obtained, and a more detailed analysis (such as use of the Cockcroft-Gault nomogram) of renal function was not available from the database.

Extensive preoperative and postoperative data were obtained on each patient, described in detail in a previous publication.[34] Statistical comparisons of these variables in the three groups of patients categorized by serum creatinine concentration were performed by chi-square test, Fisher's exact test, and Mantel-Haenszel test, when appropriate, for categorical variables and by Kruskal-Wallis tests for continuous variables. Length-of-stay variables were analyzed using Kaplan-Meier analysis censoring for death before discharge. Wilcoxon's rank-sum and log-rank test statistics were used to compare strata. To ascertain if renal failure was independently associated with adverse outcomes that were dichotomous in nature, multivariable analyses were performed using a logistic regression risk model.

Using the current method of mortality risk model development used by the Continuous Improvement in Cardiac Surgery Study,[2,5,35,36] as well as their patient population, we built a model to estimate the risk for death and disallowed baseline serum creatinine concentration from entering the model. The significant variables in predicting 30-day surgical death in this model were previous myocardial infarction, priority of surgery (elective, urgent, or emergent), Canadian Cardiovascular Society angina classification, age, prior heart surgery, history of peripheral vascular disease, current smoker, American Society of Anesthesiology classification, documented ST depression on an electrocardiogram, presence of audible rales, body surface area, functional status (independent, partially dependent, or totally dependent), performance of mitral valve replacement surgery, and finally, whether a procedure other than mitral or aortic valve replacement was performed. Of note, this model also considers whether CABG was performed. After the risk model was built without serum creatinine concentration, the two groups with elevated serum creatinine concentrations were subsequently entered to determine their effect.

Logistic regression models were analyzed using a forward, stepwise selection method with the model entry criterion set at P less than 0.25, allowing SAS (SAS Institute Inc, Cary, NC) to select the best-fit model, and P less than 0.05 as the model exit criterion, respectively. The models were evaluated by both the predictive power of the model using the concordance or C-index and the Hosmer-Lemeshow goodness-of-fit test statistic.[37,38]

Five different outcome variables (30-day surgical death and four groups of postoperative complications) were examined with multivariable logistic regression analysis. The four groups of postoperative complications studied included the presence or absence of: (1) bleeding (defined as disseminated intravascular coagulopathy, gastrointestinal bleeding, or return to the operating room for cardiothoracic bleeding), (2) infections (defined as pneumonia or harvest site wound, chest wound, mediastinitis, or endocarditis infections), (3) cardiac complications (defined as cardiac arrest or congestive heart failure symptoms), and (4) respiratory complications (defined as mechanical ventilation for $>$48 hours or the need for reintubation). These clinical variables were examined because renal failure results in physiological abnormalities that could potentially predispose to several of these events.[32]

Because cost data were not available, length-of-stay variables were developed and analyzed as surrogates for cost. Postoperative length of stay was defined as the time from surgery to discharge. Total length of stay was defined as the time from admission to discharge. In the VA health care system, medical care days are not tracked separately from non–medical care days (for example, days within the hospital that a patient awaited discharge for transportation reasons). Thus, the length-of-stay data may be biased because greater than 50% of VA patients travel in excess of 50 miles for inpatient procedures. The median distance from home to the center at which the surgical procedure was performed for patients with serum creatinine levels less than 1.5 mg/dL and 1.5 to 3.0 mg/dL was 90 miles. A stratified Kaplan-Meier was used to differentiate whether the impact of renal function was an independent predictor of length of stay.

RESULTS

The mean age of the patient population was 65.7 years, and 97% were men. Eighteen percent of the patients had undergone prior heart surgery. Of the 834-patient study population, 76.4% had a baseline serum creatinine level less than 1.5 mg/dL; 21.9%, between 1.5 and 3.0 mg/dL; and 1.7%, greater than 3.0 mg/dL. Median total (preoperative and postoperative) length of stay for the entire group was 17.0 days, whereas median postoperative length of stay was 11.0 days. The

30-day surgical mortality rate for the study population was 8.6%.

The characteristics of patients categorized by baseline serum creatinine concentrations are listed in Table 1. Median serum creatinine concentrations in the three study groups were 1.1, 1.7, and 5.5 mg/dL. In general, patients with a serum creatinine level of 1.5 mg/dL or greater tended to be older; have a greater incidence of previous myocardial infarction; more frequently have a history of diabetes mellitus, peripheral vascular disease, hypertension, and prior heart surgery; and have a higher American Society of Anesthesiology classification. The frequency of concomitant CABG procedure was 46%, 60%, and 50% in the groups with serum creatinine concentrations less than 1.5, 1.5 to 3.0, and greater than 3.0 mg/dL, respectively. As noted in the Methods section, all these variables, including CABG, were eligible for entry in our model-building process. Patients with a serum creatinine level of 1.5 to 3.0 mg/dL also more frequently had active endocarditis and current digoxin and diuretic use than the group with a serum creatinine level less than 1.5 mg/dL. The frequency with which a mechanical valve replacement procedure (versus biological valve or other type of procedure) was performed in patients with baseline serum creatinine levels less than 1.5, 1.5 to 3.0, and greater than 3.0 mg/dL was 47%, 57%, and 64%, respectively.

Several post–valve surgery outcomes in the three groups of patients, categorized by baseline serum creatinine concentration, are listed in Table 2. Univariately, the serum creatinine grouping was significantly associated with increased 30-day surgical mortality, as well as cardiac arrest, low cardiac output, heart block requiring pacemaker, prolonged ventilation, and neurological (coma for >24 hours and stroke), gastrointestinal (bleeding), and renal (renal failure requiring dialysis after discharge) complications. One infectious complication (pneumonia), but not other infectious complications (mediastinitis, chest wound infection, and endocarditis), had a significant difference among the three groups of patients.

Using multivariable logistic regression analysis, mild to moderate renal failure (serum creatinine, 1.5 to 3.0 mg/dL) compared with normal renal function (serum creatinine <1.5 mg/dL) significantly increased 30-day surgical mortality (P = 0.001). The C-index was 0.692 for the mortality model without serum creatinine level;

Table 1. Characteristics of Study Subjects Categorized by Baseline Serum Creatinine Concentration

Variable	Serum Creatinine <1.5 mg/dL (n = 637)	Serum Creatinine 1.5-3.0 mg/dL (n = 183)	Serum Creatinine >3.0 mg/dL (n = 14)	*P*
Median serum creatinine (mg/dL)	1.1	1.7	5.5	<0.001
Age (y)	64.7	69.1	65.3	<0.001
Preoperative balloon pump	10 (2)	4 (2)	1 (7)	0.171
Prior myocardial infarction	148 (23)	70 (38)	8 (57)	0.001
Prior heart surgery	100 (16)	48 (26)	2 (14)	0.007
New York Heart Association classification III or IV	388 (61)	127 (70)	12 (86)	0.152
Angina functional classification III or IV	203 (32)	67 (36)	4 (29)	0.449
American Society Anesthesiology classification IV and V	316 (50)	123 (67)	9 (64)	0.001
Urgent or emergent surgical priority	59 (9)	25 (14)	2 (14)	0.220
Active endocarditis	16 (3)	12 (7)	0 (0)	0.045
History of cerebral vascular disease	118 (19)	44 (24)	4 (29)	0.184
History of peripheral vascular disease	122 (19)	73 (40)	4 (29)	0.001
History of hypertension	301 (47)	115 (63)	11 (79)	0.001
History of chronic obstructive lung disease	99 (16)	40 (22)	3 (21)	0.122
Presence of diabetes mellitus	89 (14)	39 (21)	4 (29)	0.006
Current smoker	145 (23)	36 (20)	1 (7)	0.273
Current bronchodilator use	110 (17)	49 (27)	0 (0)	0.104
Current diuretic use	296 (46)	125 (68)	5 (36)	0.001
Current digoxin use	188 (29)	78 (43)	3 (21)	0.012
Mechanical valve	364 (57)	86 (47)	9 (64)	0.100

NOTE. Values expressed as number (percent) unless otherwise noted.

Table 2. Postoperative Complication Rates in Three Groups of Patients Undergoing Cardiac Valve Surgery Classified by Baseline Serum Creatinine Concentration

Complication	Serum Creatinine <1.5 mg/dL (n = 637)	Serum Creatinine 1.5-3.0 mg/dL (n = 183)	Serum Creatinine >3.0 mg/dL (n = 14)	*P*
30-day mortality (%)	6.0	15.8	35.7	<0.001
Myocardial infarction (%)	5	5	21	0.071
Cardiac arrest (%)	3	10	21	0.001
Low cardiac output (%)	18	32	21	<0.001
Heart block requiring pacemaker (%)	12	15	36	0.029
Renal failure requiring dialysis at discharge (%)	2	10	21	0.001
On ventilator >24 h (%)	15	27	21	0.001
Reintubated (%)	8	13	14	0.092
Coma >24 h (%)	2	5	14	0.001
Stroke (%)	4	9	7	0.007
Gastrointestinal bleeding (%)	2	4	14	0.009
Pneumonia (%)	6	14	14	0.001

this increased to 0.711 when the two serum creatinine variables (serum creatinine levels of 1.5 to 3.0 and >3.0 mg/dL) were added to the baseline model. This change in C-index, although in the direction toward improved predictive power, was not statistically significant.

Also using multivariable logistic regression analysis, mild to moderate renal failure (serum creatinine, 1.5 to 3.0 mg/dL) compared with normal renal function (serum creatinine < 1.5 mg/dL) significantly increased bleeding complications (defined as disseminated intravascular coagulation, gastrointestinal hemorrhage, or thoracic hemorrhage sufficient to require reoperation; $P = 0.023$); cardiac complications (defined as cardiac arrest and low cardiac output; $P = 0.002$); and ventilatory complications (defined as >48 hours on mechanical ventilation and/or reintubation; $P = 0.020$) independent of other variables. Multivariable logistic regression analysis did not show that mild to moderate renal failure (serum creatinine, 1.5 to 3.0 mg/dL) was associated with an increase in selected infectious complications (pneumonia, mediastinitis, chest wound infection, or endocarditis; $P = 0.0972$) over the group with normal renal function (serum creatinine <1.5 mg/dL).

Multivariable comparisons were performed using the group with baseline serum creatinine level less than 1.5 mg/dL as the reference for comparison. The odds ratios with 95% confidence intervals (CIs) when comparing patients with a serum creatinine level less than 1.5 mg/dL with those with a serum creatinine level of 1.5 to 3.0 mg/dL were 2.45 (95% CI, 1.43 to 4.19) for 30-day mortality, 1.81 (95% CI, 1.09 to 3.03) for bleeding, 1.62 (95% CI, 1.08 to 2.44) for ventilatory complications, and 2.25 (95% CI, 1.34 to 3.77) for cardiac complications. Multivariable analysis with regard to selected infectious complications (pneumonia, chest wound infection, mediastinitis, and endocarditis) showed no significant effect when a serum creatinine level of 1.5 to 3.0 mg/dL was added to the original model (odds ratio, 1.48; 95% CI, 0.93 to 2.36).

With regard to risk for bleeding complications and renal function, data listed in Table 3 indicate a significant increase in average number of units of transfused red blood cells and fresh frozen plasma, but not platelets, in the intraoperative and postoperative periods in the group of patients with a serum creatinine concentration of 1.5 to 3.0 mg/dL. The percentage of patients with

Table 3. Transfusions in Patients Undergoing Cardiac Valve Surgery Categorized by Baseline Serum Creatinine Concentration

	Serum Creatinine <1.5 mg/dL	Serum Creatinine 1.5-3.0 mg/dL	*P*
Red blood cells	3.27 (n = 459)	6.01 (n = 156)	<0.001
Fresh frozen plasma	1.90 (n = 261)	3.30 (n = 97)	<0.002
Platelets	5.18 (n = 293)	7.69 (n = 93)	0.069

NOTE. Values expressed as average number of units transfused intraoperatively or postoperatively.

baseline serum creatinine concentrations less than 1.5, 1.5 to 3.0, and greater than 3.0 mg/dL administered red blood cells (72%, 85%, and 79%, respectively), fresh frozen plasma (41%, 53%, and 50%, respectively), but not platelet transfusions (46%, 51%, and 64%, respectively) increased significantly ($P = 0.001$; $P = 0.004$; $P = 0.186$, respectively) in parallel with the magnitude of increase in serum creatinine level.

With regard to length of stay, stratified Kaplan-Meier analysis showed univariately that the group with a baseline serum creatinine level of 1.5 to 3.0 mg/dL also had a significantly longer total length of stay than the group with a baseline serum creatinine level less than 1.5 mg/dL (16 versus 20 days, respectively; $P < 0.001$).

DISCUSSION

Preoperative assessment before cardiac and other types of surgery has traditionally focused on the cardiovascular and pulmonary systems.[39-41] In 1992, Browner et al[4] suggested that impaired renal function is an important predictor of surgical mortality. In this study, including 474 male veterans with either known coronary artery disease or at high risk for coronary artery disease, a reduced estimated creatinine clearance was a significant (odds ratio, 6.8; 95% CI, 2.8 to 16.0) independent predictor of postoperative mortality after noncardiac surgery.[4] There is, however, limited information on the impact of renal failure on cardiovascular surgical outcomes.

A modest experience with cardiac surgery, including valve replacement surgery, in patients with end-stage renal disease undergoing chronic renal replacement therapy has been published.[24-30] These studies show that cardiac surgery can be successfully performed in dialysis patients with subsequent improved functional status. However, a relatively high rate of complications and mortality was observed.[24-30]

With regard to lesser degrees of renal failure, the presence of mild to moderate renal dysfunction has been reported to significantly increase surgical mortality after carotid endarterectomy, but not after elective repair of infrarenal abdominal aortic aneurysms.[42-44] We and others have found that mild renal failure (serum creatinine, 1.5 to 3.0 mg/dL) significantly increases mortality after CABG.[6,12,13,31] Regarding cardiac valve replacement, Scott et al[16] reported in 1985 that preoperative renal dysfunction was a significant determinant of surgical mortality in patients undergoing valve replacement for aortic stenosis. Subsequently, Grover et al,[2] using a large VA database, found that the mean serum creatinine concentration was significantly less (1.3 mg/dL) in survivors than nonsurvivors (1.7 mg/dL; $P < 0.001$) of cardiac valve surgery.

The present analyses confirm and extend some of these previous observations. We found that several adverse outcomes occurred with significantly greater frequency in patients with preoperative serum creatinine levels of 1.5 to 3.0 mg/dL compared with patients with serum creatinine concentrations less than 1.5 mg/dL. Multivariable logistic regression analysis found that serum creatinine levels of 1.5 to 3.0 mg/dL were independently associated with significantly increased 30-day surgical mortality. Stratified Kaplan-Meier analysis found that preoperative serum creatinine levels of 1.5 to 3.0 mg/dL were also associated with increased length of stay. Collectively, these observations clearly document that preoperative mild to moderate renal failure is significantly associated with adverse outcome and enhanced resource use after cardiac valve surgery in the studied population.

The present study also delineates some of the specific complications encountered with increased frequency in patients with mild renal failure undergoing heart valve surgery. Our multivariable analysis found that mild renal failure was significantly associated with selected bleeding, respiratory, and cardiac complications independent of other variables. Our results with regard to a significant association of mild renal failure with increased bleeding complications after cardiac valve surgery is corroborated by our finding of a significant increase in red blood cell and fresh frozen plasma transfusions administered to the group with renal failure.

Two observations regarding our results are particularly worthy of comment. First, the degree of renal failure (median serum creatinine, 1.7 mg/dL) present in the group with mild renal failure that we studied was modest and would be considered by many clinicians to be unlikely to adversely affect surgical outcome per se. It is noteworthy, however, that two other studies found that a similar, modest degree of renal failure is associated with adverse outcome after general and heart valve replacement surgery.[2,4] Moreover, a recent case-control study showed that induction of even a very modest degree of radio contrast–associated renal failure significantly increased mortality and the occurrence of bleeding and respiratory complications.[45]

Second, the findings of the present study are remarkably consistent with those obtained in a multivariable analysis of the impact of mild renal failure on CABG outcome that we recently performed.[31] Although the absolute rate of selected cardiac, bleeding, and respiratory complications that we observed after valve surgery in patients with a serum creatinine concentration less than 1.5 mg/dL (7%, 8%, and 16%, respectively) was approximately twofold greater than that observed after CABG in patients with a serum creatinine concentration less than 1.5 mg/dL, the rate of these complications was approximately doubled in patients with mild renal failure after both CABG and valve surgery. Together, these observations suggest that mild renal failure is an important, independent risk factor in at least two types of cardiac surgery, and the impact of mild renal failure to increase morbidity is similar in the two operations and occurs independently of the absolute level of risk.

There are several limitations to the present analysis. First, the observational nature of our study does not allow us to delineate pathophysiological mechanisms involved to explain our results. Also, even though we analyzed a very comprehensive set of variables, it is possible that we did not identify and analyze all potential confounding factors. Second, the nature of the VA patient population that we studied does not allow us to be able to comfortably generalize our observations to other patient populations. Third, we used a discretionary definition to categorize the presence and degree of renal failure. It is likely that some of our smaller, older patients undergoing valve surgery with a serum creatinine concentration less than 1.5 mg/dL had mild to moderate renal failure. Also, we were not able to clearly ascertain if the mild renal failure present was either hemodynamically mediated or caused by chronic intrinsic renal disease. Together, these factors limit somewhat our ability to more accurately assess the contribution of mild renal failure to adverse outcomes after cardiac valve surgery. Finally, the number of patients that we analyzed with more advanced renal failure (serum creatinine >3.0 mg/dL) is limited. This small sample size prevents ascertainment of whether more advanced degrees of renal failure are associated with a greater rate of complications.

In summary, we find that a preoperative serum creatinine level of 1.5 to 3.0 mg/dL is significantly and independently associated with increased 30-day mortality and selected bleeding, cardiac, and respiratory complications after cardiac valvular surgery. Although further study is required to delineate the mechanism(s) of this adverse effect, this population of patients should be considered at enhanced risk for adverse outcome after valve surgery.

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