Usefulness of a Simple Clinical Risk Prediction Method, Modified ACEF Score, for Transcatheter Aortic Valve Implantation

Takahide Arai, MD; Thierry Lefèvre, MD; Kentaro Hayashida, MD, PhD; Yusuke Watanabe, MD; Stephen A. O'Connor, MD; Thomas Hovasse, MD; Mauro Romano, MD; Philippe Garot, MD; Erik Bouvier, MD; Bernard Chevalier, MD; Marie-Claude Morice, MD

Background: We assessed the predictive accuracy of a simple risk score, modified age, creatinine clearance, ejection fraction (ACEFmodif) score, for outcome of transcatheter aortic valve implantation (TAVI).

Methods and Results: We prospectively included 703 consecutive patients undergoing TAVI. Patients were divided into low, middle and high ACEFmodif tertiles. Increased ACEFmodif score was associated with a significantly higher 1-year mortality rate (22%, 28% and 36%, $P < 0.01$) and higher risk of acute kidney injury (AKI; 10%, 10% and 22%, $P < 0.01$). On multivariate logistic regression analysis, ACEFmodif score was the only independent predictor of AKI. On multivariate Cox regression, ACEFmodif score was an independent predictor of 1-year cumulative mortality. Although the area under curve (AUC) showed that all risk scores poorly predicted the incidence of AKI and 1-year cumulative mortality, ACEFmodif score was more efficient in predicting the incidence of AKI compared with STS, LES and ES II (AUC, 0.61, 0.55, 0.54, 0.57, respectively). Furthermore, ACEFmodif score had similar accuracy in predicting 1-year mortality compared with other risk scores (AUC, 0.61, 0.61, 0.61, 0.61, respectively).

Conclusions: ACEFmodif score may provide useful information for predicting AKI, 30-day and 1-year mortality in patients undergoing TAVI, but these results need further confirmation. (*Circ J* 2015; **79**: 1496–1503)

Key Words: Acute kidney injury; Modified age, creatinine clearance, ejection fraction score; Severe symptomatic aortic stenosis; Transcatheter aortic valve implantation

Transcatheter aortic valve implantation (TAVI) is being increasingly used as a treatment option for patients with severe symptomatic aortic stenosis (AS) who are considered at high risk for surgical aortic valve replacement (SAVR).^{1–4} Despite its minimally invasive nature, TAVI is invariably associated with complications that may affect outcomes. Consequently, pre-procedure evaluation of risks should be carried out thoroughly. Although risk assessment scores such as the Logistic European System for Cardiac Operative Risk Evaluation (LES), the European System for Cardiac Operative Risk Evaluation Score II (ES II) and the Society of Thoracic Surgeons (STS) predicted risk mortality score have proved useful,^{5,6} their predictive value remains inadequate despite a relatively high number of variables.

Age, creatinine clearance, ejection fraction (ACEF) score is a novel and simple scoring method that includes only 3 variables.⁷ This simple scoring system has been tested in patients

undergoing coronary artery bypass grafting (CABG) and percutaneous coronary intervention (PCI) and has been shown to be helpful in predicting outcome.^{8,9} The modified ACEF (ACEFmodif) score includes creatinine clearance as a semi-continuous variable instead of serum creatinine and has been reported to increase the accuracy of the original ACEF score among PCI patients.^{10–12} The usefulness of this score in patients undergoing TAVI, however, has not been previously assessed in a large cohort of patients. The aim of this study was, therefore, to assess the accuracy of the ACEFmodif score in predicting the outcome of patients undergoing TAVI.

Methods

Study Design

From October 2006, all consecutive high-risk patients with severe symptomatic AS treated with TAVI were prospectively

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Department of Interventional Cardiology (T.A., T.L., K.H., Y.W., S.A.O., T.H., P.G., E.B., B.C., M.-C.M.), Department of Cardiovascular Surgery (M.R.), Institut Cardiovasculaire Paris Sud, Massy, France; Department of Cardiology, Keio University School of Medicine, Tokyo (K.H.); and Department of Cardiology, Teikyo University School of Medicine, Tokyo (Y.W.), Japan

Mailing address: Thierry Lefèvre, MD, FESC, FSCAI, Department of Interventional Cardiology, Hôpital Privé Jacques Cartier, Générale de Santé, 6 avenue du Noyer Lambert, FR-91300 Massy, France. E-mail: t.lefevre@angio-icps.com

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Table 1. Baseline Clinical Characteristics

	Low ACEF modif (0.6–2.1) (n=236)	Middle ACEF modif (2.2–3.8) (n=237)	High ACEF modif (3.9–9.6) (n=230)	P-value
Baseline characteristics				
Age (years)	80.7±7.6	84.1±5.0	85.2±5.7	<0.01
Male	106 (45%)	116 (49%)	136 (59%)	<0.01
BMI (kg/m ²)	27.7±5.4	25.4±4.0	24.3±3.3	<0.01
BSA (m ²)	1.79±0.22	1.73±0.19	1.70±0.18	<0.01
NYHA classification (III/IV)	190 (81)	204 (86)	196 (85)	0.27
Peripheral artery disease	78 (33)	66 (28)	78 (34)	0.34
Prior MI	18 (8)	21 (9)	29 (13)	0.18
Prior PCI	47 (20)	56 (24)	75 (33)	<0.01
Prior CABG	35 (15)	26 (11)	32 (14)	0.35
Prior cardiac surgery	40 (17)	30 (13)	32 (14)	0.42
Prior stroke	26 (11)	12 (5)	23 (10)	0.07
Atrial fibrillation	70 (30)	66 (28)	80 (35)	0.27
Diabetes mellitus	59 (25)	54 (23)	50 (22)	0.68
Hypertension	169 (73)	151 (64)	156 (68)	0.09
Dyslipidemia	121 (52)	120 (51)	108 (47)	0.52
Cancer	32 (14)	28 (12)	32 (14)	0.75
COPD	190 (81)	204 (86)	196 (85)	0.77
Logistic EuroSCORE (%)	17.3±10.2	20.2±10.2	26.9±12.6	<0.01
EuroSCORE II (%)	5.3±4.2	7.3±4.1	10.3±5.7	<0.01
STS score (%)	5.2±4.3	7.7±5.2	9.9±6.3	<0.01
Creatinine clearance (ml/min)	76.7±26.9	52.0±13.2	34.8±11.2	<0.01
Creatinine (μmol/l)	78.2±19.1	100.7±24.1	168.3±124.5	<0.01
CKD 4	0 (0)	0 (0)	64 (28)	–
Echocardiographic data				
LVEF (%)	57.6±10.5	53.1±14.5	43.7±14.7	<0.01
Low EF	21 (9)	62 (26)	110 (48)	<0.01
AVA (cm ²)	0.66±0.14	0.62±0.14	0.62±0.15	<0.01
Mean gradient (mmHg)	48.1±16.4	47.7±16.6	45.2±17.5	0.13
AR grade (0–4)	0.86±0.78	0.88±0.74	0.91±0.73	0.77
PAP (mmHg)	45.7±12.2	47.2±14.9	51.0±13.7	<0.01

Data given as n (%) or mean±SD. ACEF, age, creatinine clearance, ejection fraction; AR, aortic regurgitation; AVA, aortic valve area; BMI, body mass index; BSA, body surface area; CABG, coronary artery bypass grafting; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; EF, ejection fraction; LVEF, left ventricle EF; MI, myocardial infarction; MR, mitral regurgitation; NYHA, New York Heart Association; PAP, pulmonary artery pressure; PCI, percutaneous coronary intervention.

included in the dedicated TAVI database. Patients with severe AS were considered candidates for TAVI if they were deemed ineligible or high risk for SAVR. The decision to proceed with TAVI was made by a dedicated heart team composed of experienced clinical and interventional cardiologists, cardiovascular surgeons and anesthesiologists. Between October 2006 and May 2013, a total of 703 patients were included. Written informed consent was obtained from all patients.

The STS score, LES, ES II and ACEFmodif score were assessed. The ACEFmodif score was calculated using the following formula: age/EF+1 point for every 10-ml/min reduction in creatinine clearance <60 ml/min/1.73 m² (up to a maximum of 6 points), as described previously.¹⁰

Vascular Access and Valve Selection

Patients were selected to undergo TAVI via the transfemoral (TF) approach or alternative approaches depending on the size, calcification and tortuosity of the ilio-femoral arterial access. In most instances, the type of valve prosthesis was selected according to the team's and the main operator's preference. The trans-subclavian (SC) or transaortic approach (TAo)

was used as an alternative in cases of unsuitable femoral arterial access in recipients of the CoreValve, and the transapical (TA), trans-subclavian, or transaortic route as the alternative to suboptimal femoral access with the Edwards valve.

Procedures

Aspirin (75–160 mg) and clopidogrel (75 mg) daily were recommended prior to TAVI. A loading dose of clopidogrel (300–600 mg) was administered to patients who were not already on clopidogrel before or immediately after the procedure. Only 1 antiplatelet therapy, usually aspirin, was associated with warfarin in the majority of patients on long-term anticoagulant therapy. A bolus of heparin (70 IU/kg) was administered at the start of the procedure to achieve an activated clotting time of 250–300 s, and the activated clotting time was measured every 30 min thereafter. All procedures were performed by an experienced team according to the standard operating procedures, as previously described.¹³

Post-Procedural Care

All patients were observed in the intensive care unit for at least

Table 2. Procedural and Post-Procedural Characteristics

	Low ACEF modif (0.6–2.1) (n=236)	Middle ACEF modif (2.2–3.8) (n=237)	High ACEF modif (3.9–9.6) (n=230)	P-value
Type of valve				0.20
Edwards valve	194 (82)	185 (78)	175 (76)	
CoreValve or another valve	42 (18)	52 (22)	55 (24)	
Approach route				
TF approach	118 (50)	123 (52)	142 (62)	0.01
TA approach	37 (16)	45 (19)	34 (15)	0.46
TAo approach	77 (33)	61 (26)	48 (21)	0.01
Valve size (mm)	26.1±2.2	26.1±2.3	26.2±2.4	0.81
Early experience	15 (6)	19 (8)	16 (7)	0.77
Post-procedural variables				
Length of hospital stay (days)	11.6±7.7	11.8±8.8	11.7±10.2	0.98
Procedural success	221 (94)	210 (89)	213 (93)	0.13
30-day mortality	21 (8)	33 (13)	42 (18)	<0.01
30-day combined safety endpoint	35 (15)	53 (23)	58 (26)	<0.01
Need for PCI	4 (2)	2 (1)	5 (2)	0.51
Cerebrovascular accidents	2 (1)	7 (3)	9 (4)	0.18
AKI	25 (10)	25 (10)	49 (22)	<0.01
Major vascular complication	14 (6)	28 (12)	23 (10)	0.08
Major bleeding	7 (3)	7 (3)	4 (2)	0.87
RBC transfusion	61 (28)	64 (29)	67 (31)	0.85
Pacemaker implantation	20 (9)	23 (10)	20 (9)	0.85
2 valve implantation	7 (3)	12 (5)	5 (2)	0.20
Post-procedural AR ≥grade 2	30 (13)	47 (20)	56 (25)	<0.01
Need for any cardiac surgery	5 (2)	7 (3)	5 (2)	0.63

Data given as n (%) or mean±SD. AKI, acute kidney injury; RBC, red blood cell; TA, transapical; TAo, transaortic; TF, transfemoral. Other abbreviations as in Table 1.

24 h after Edwards valve implantation or 72 h after CoreValve implantation (patients without previous pacemaker). Dual anti-platelet therapy was continued for 1–6 months and, thereafter, aspirin was continued indefinitely.

Follow-up

After the procedure, all patients were assessed by a physician at 1, 3, 6 and 12 months postoperatively and annually thereafter. Additional follow-up data were collected via telephone interviews and contact with the patients' family physicians.

Endpoints

The main endpoints of this study were the incidence of acute kidney injury (AKI) and all-cause mortality at 30-day and 1-year follow-up. All adverse events were assessed according to the Valve Academic Research Consortium (VARC) criteria. Adverse events were prospectively collected by the research technicians and validated by the cardiologists.

Statistical Analysis

All statistical analysis was performed using SPSS version 21.0 (Chicago, IL, USA). Continuous variables are expressed as mean±SD or with the corresponding interquartile range (IQR). Dichotomous variables are expressed as counts and percentages. Comparison between 3 groups was performed using Pearson's bivariate test and the chi-squared test for categorical covariates, and 1-way ANOVA for continuous covariates. Univariate logistic regression analysis was performed to investigate the factors independently associated with AKI. Subsequently, multivariate analysis was performed using variables with

$P<0.10$ on univariate analysis in order to examine their independent association with AKI. Survival analysis was performed using the Kaplan-Meier method. Univariate Cox regression analysis was performed to examine the variables related to 1-year cumulative mortality. Subsequently, multivariate analysis was performed using variables with $P<0.10$ on univariate analysis in order to examine their independent association with 1-year cumulative mortality. Receiver operating characteristic (ROC) analysis with the area under curve (AUC) as a measurement of accuracy was used to compare the accuracy between different risk scores. $P<0.05$ was considered significant.

Results

Baseline Characteristics and Post-Procedural Outcome

Of the 703 study patients, 236 were in the lowest tertile (ACEFmodif score 0.6–2.1), 237 in the middle tertile (ACEFmodif score 2.2–3.8), and 230 in the highest tertile (ACEFmodif score 3.9–9.6). Baseline characteristics are given in Table 1. Variations in baseline characteristics between the 3 study groups resulted in significant differences in the mean logistic EuroSCORE (17.3 vs. 20.2 vs. 26.9, $P<0.001$), EuroSCORE II (5.3 vs. 7.3 vs. 10.3, $P<0.001$) and STS score (5.2 vs. 7.7 vs. 9.9, $P<0.001$). Procedural characteristics are listed in Table 2. The Edwards valve was used in 554 patients (78%) and other valves, mainly the CoreValve, in 149 (22%). Although there were no significant differences between the 3 groups regarding the use of the TA approach (16% vs. 19% vs. 15%, $P=0.46$), there was a significant difference between the groups with respect to the use of the TAo approach (33% vs.

Table 3. Predictors of AKI

	Univariate analysis			Multivariate analysis		
	OR	95% CI	P-value	OR	95% CI	P-value
Diabetes	1.18	0.72–1.93	0.49			
End-stage renal disease	3.41	1.11–10.03	0.03	1.72	0.48–6.43	0.38
STS score (per 1-point increase)	1.00	0.96–1.03	0.97			
EuroSCORE (per 1-point increase)	1.01	0.99–1.03	0.10			
EuroSCORE II (per 1-point increase)	1.04	1.00–1.08	0.04	1.01	0.96–1.06	0.61
ACEFmodif (per 1-point increase)	1.25	1.11–1.41	<0.01	1.21	1.04–1.41	0.01

End-stage renal disease, creatinine clearance <15 ml/min/1.73 m². ACEFmodif, modified ACEF score; EuroSCORE, European System for Cardiac Operative Risk Evaluation; STS, Society of Thoracic Surgeons. Other abbreviations as in Tables 1,2.

Figure 1. Cumulative all-cause mortality vs. modified age, creatinine clearance, ejection fraction (ACEF) tertile.

26% vs. 21%, $P=0.01$) and TF approach (50% vs. 52% vs. 62%, $P=0.01$). There was no significant difference between the 3 groups in the number of early-experience cases, which was defined as the first 50 cases. While no significant differences were observed in the procedural success rates between the 3 groups, the 30-day mortality rate (8% vs. 13% vs. 18%, $P<0.01$), 30-day combined safety endpoints (15% vs. 23% vs. 26%, $P<0.01$), and the incidence of AKI (10% vs. 10% vs. 22%, $P<0.01$), significantly increased with ACEFmodif tertile.

Predictors of AKI

Predictors of AKI were evaluated on logistic regression analysis (Table 3). On univariate analysis, diabetes, creatinine clearance (<15 ml/min/1.73 m²) and ACEFmodif were significant predictors of AKI. On multivariate logistic regression, ACEFmodif score was the only independent predictor of AKI.

Impact of ACEFmodif Score on Mid-Term Mortality After TAVI

The median follow-up period of this cohort was 406 days (IQR, 35–730). Follow-up at 1 year was complete in 422 (60%) of the 703 study patients. Cumulative all-cause mortality rates at 1 year according to ACEFmodif tertile were 22%, 28%, and 36%, respectively. Cumulative all-cause mortality rates were calculated using the Kaplan-Meier method and compared using log-rank test (Figure 1). The mortality rate in the low ACEFmodif tertile was significantly lower in comparison with

the middle ACEFmodif tertile and high ACEFmodif tertile. Similarly, cumulative cardiovascular mortality rates at 1 year according to ACEFmodif tertile were 14%, 17%, and 25%, respectively. Cumulative cardiovascular death rate in the low ACEFmodif tertile was significantly lower in comparison with the middle ACEFmodif tertile and high ACEFmodif tertile (Figure 2).

Predictors of 1-Year Cumulative Mortality

Predictors of 1-year cumulative mortality were evaluated on Cox regression analysis (Table 4). On univariate analysis, TA approach, post-procedural aortic regurgitation (AR; $\geq$ grade 2), STS score, EuroSCORE, EuroSCORE II and ACEFmodif score were significant predictors of 1-year mortality. On multivariate Cox regression, TA approach, post-procedural AR ($\geq$ grade 2) and ACEFmodif score were independent predictors of 1-year cumulative mortality (Figure 3).

Risk Score Accuracy

According to AUC, all risk scores poorly predicted AKI, 30-day and 1-year cumulative mortality (Figure 4), but ACEFmodif had better predictive value for AKI compared with other risks and the same predictive value for 30-day and 1-year mortality as other risk models.

	HR	95% CI	P-value
Low EF	1.25	0.89–1.75	0.19
COPD	1.31	0.94–1.82	0.11
Male	1.14	0.83–1.56	0.40
End-stage renal disease	1.36	0.50–3.68	0.54
TA approach	1.71	1.21–2.42	<0.01
TF approach	0.84	0.62–1.15	0.30
Post-procedural AR $\geq$ grade 2	1.68	1.18–2.39	<0.01
STS score (per 1-point increase)	1.03	1.01–1.05	<0.01
EuroSCORE (per 1-point increase)	1.02	1.00–1.03	<0.01
EuroSCORE II (per 1-point increase)	1.05	1.03–1.08	<0.01
ACEFmodif (per 1-point increase)	1.43	1.17–1.74	<0.01

End-stage renal disease, creatinine clearance <15 ml/min/1.73m². Abbreviations as in Tables 1–3.

Prediction of AKI and Mortality According to Access

According to AUC, ACEFmodif had a better predictive value for 30-day mortality compared with other risk scores in the non-TF cohort, although ES II had a better predictive value for 30-day mortality compared with other risk scores in the TF

cohort. Furthermore, ACEFmodif also had the same predictive value (albeit poor), for AKI and 1-year mortality as other risk models both in the TF cohort and non-TF cohort ([Table S1](#)).

Discussion

The present study indicates that ACEFmodif score might provide useful information for predicting AKI, 30-day and 1-year mortality in patients undergoing TAVI. This simple scoring method was tested in patients undergoing CABG or PCI and proved valuable in predicting outcome. So far, only 1 study has investigated the usefulness of ACEF score in predicting outcome in TAVI patients.¹⁴ To the best of our knowledge, the present study is the first to show that ACEFmodif score has the potential to predict outcome in TAVI patients. In addition, ACEF score has been reported to be a good predictor of AKI after PCI.¹⁵ The present study is also the first to suggest that ACEFmodif

score is a good predictor of AKI after TAVI. ACEF score is a very simple scoring tool that includes only 3 variables. These 3 variables have been shown to be associated with the prognosis of CABG and PCI,^{16–18} and have also been investigated in TAVI patients. With respect to age, a number of studies have shown that TAVI can be performed in elderly patients, but the relationship between age and prognosis is still under debate.^{19,20} With regard to EF, the majority of studies have shown that low EF is a predictor of poor outcome.^{21,22} Nevertheless, 1 study has shown that TAVI is associated with earlier recovery of EF and good outcome.²³ These contrasting findings account for the fact that the relationship between low EF and the TAVI outcome has not yet been elu-

citated. With regard to renal insufficiency, many studies have shown that pre-procedural renal failure is a predictor of 30-day and 1-year mortality.²⁴

The use of multiple clinical variables should improve the accuracy of risk models, although this accuracy may ultimately be negatively affected by the desire to create the perfect model.²⁵ The LES, ES II and STS scores have often been used for risk assessment before TAVI,^{6,26,27} but even though they include many variables, these scores are not very reliable (AUC<0.7).²⁶ The ACEFmodif score is a very simple scoring tool that includes only 3 variables and seems to be quite easy to use. This score has been shown to be as accurate as the LES score, which includes 17 clinical variables, in patients undergoing elective CABG.⁷ The present study also showed that ACEFmodif score has a superior predictive value for AKI compared with other risk models.

In the present study, ACEFmodif score had better predictive value for AKI compared with other risk models both in the TF and non-TF cohort, as well as better predictive value for 30-day mortality compared with other risk scores in the non-TF cohort. In addition, ACEFmodif had the same predictive value for mid-term mortality as other risk models both in the TF and non-TF cohorts.

This study showed that not only ACEFmodif score, but also the TA approach was a predictor of 1-year cumulative mortality. Gilard et al. also reported in the FRANCE 2 study that the TA approach was significantly associated with increased 1-year mortality.²⁸ The TAO approach is currently proposed as an alternative to the TA approach for patients in whom the TF approach is not feasible.²⁹ Furthermore, this study showed that post-procedural AR ($\geq$ grade 2) was a predictor of 1-year mortality. Some reports have shown that even mild AR is associated with poorer outcome.^{6,30,31} Next-generation devices designed to reduce post-procedural AR are now being used.

ACEFmodif score uses creatinine clearance instead of serum creatinine level. Among patients undergoing CABG, creatinine clearance has been shown to be a better predictor when compared with serum creatinine.^{32,33} In addition, ACEFmodif score has been reported to increase the accuracy of the original ACEF score among PCI patients. Furthermore, the stage of chronic kidney disease on the basis of the estimated glomerular filtration rate has been shown to be strongly related to TAVI outcome.²⁴ Thus, ACEFmodif is potentially a better predictor than the original ACEF score in TAVI patients.

ACEF score has been reported to be a good predictor of AKI and mortality after PCI.^{10,15} Consequently, this study focused on the predictive value of ACEFmodif for AKI and mortality. The predictive value of ACEFmodif on cerebrovascular events, myocardial infarction and life-threatening bleeding after TAVI were also evaluated on logistic regression analysis. ACEFmodif, however, was not a good predictor of cerebrovascular events (OR, 1.22; 95% CI: 0.95–1.57, $P=0.11$), myocardial infarction (OR, 0.80; 95% CI: 0.37–1.75, $P=0.59$) and life-threatening bleeding (OR, 0.99; 95% CI: 0.83–1.17, $P=0.89$).

This study shows that a simple and objective score such as ACEFmodif is very useful for predicting outcome in patients undergoing TAVI. It is important to emphasize, however, that currently available risk scores including ACEF score, LES, ES II and STS score cannot provide a thorough assessment of the risks before TAVI. Risk evaluation should be carried out for each individual case by the heart team, which consists of experienced interventional cardiologists, cardiac surgeons, anesthesiologists and imaging specialists as well as geriatricians in difficult cases.

Study Limitations

The present study has several limitations that should be addressed. First, this was a retrospective observational single-center study carried out in a limited number of patients. Further studies with larger cohorts and multiple-center analysis are required to confirm our result. Second, the risk-adjusted multivariate model in this study did not include all possible residual variables because of the limited size of the study. Third, the rate of 1-year follow-up was 60% in all patients. This impaired the validity of the identification of predictors of 1-year mortality. The results need further confirmation. Finally, the mean follow-up period was 406 days, and long-term follow-up is needed to investigate the impact of ACEF score on long-term outcome.

Conclusions

ACEFmodif score may provide useful information for predicting AKI, 30-day and 1-year mortality in patients undergoing TAVI, but the present results need further confirmation.

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Conflicts of Interest

T.L. is a proctor for transfemoral-TAVI for Edwards Lifesciences, and a consultant for Symetis and Direct Flow Medical. M.R. is a proctor for transapical-TAVI for Edwards Lifesciences. K.H. is a proctor for transfemoral-TAVI for Edwards Lifesciences. B.C. is a consultant for Medtronic.

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Supplementary Files

Supplementary File 1

Table S1. Discrimination parameters for predicting AKI and mortality according to access

Please find supplementary file(s);
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