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Screening for significant atherosclerotic renal artery stenosis with a regression model in patients undergoing transradial coronary angiography/intervention

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Abstract: Objective: Early detection of atherosclerotic renal artery stenosis (ARAS) is clinically important with respect to blood pressure control, prevention of renal insufficiency, and even improving survival. We investigated whether the presence of significant ARAS (luminal diameter narrowing ≥70%) could be predicted using a logistic regression model before coronary angiography/intervention. Methods: Initially, we developed a logistic regression model for detecting significant ARAS based upon clinical and angiographic features and biochemical measurements in a cohort of 1 813 patients undergoing transfemoral coronary and renal angiography. This model was then prospectively applied to an additional 495 patients who received transradial renal angiography to ascertain its predictive accuracy for the presence of significant ARAS. Results: Multivariate regression analysis revealed that older age (≥65 years), resistant hypertension, type 2 diabetes, creatinine clearance (Ccr) ≤60 ml/min, and multivessel coronary disease were independent predictors for significant ARAS. A logistic regression model for detecting ARAS by incorporating conventional risk factors and multivessel coronary disease was generated as: $P/(1-P)=\exp(-2.618+1.112[\text{age}\geq 65\text{ years}]+1.891[\text{resistant hypertension}]+0.453[\text{type 2 diabetes}]+0.587[\text{Ccr}\leq 60\text{ ml/min}]+2.254[\text{multivessel coronary disease}])$. When this regression model was prospectively applied to the additional 495 patients undergoing transradial coronary and renal angiography, significant ARAS could be detected with a sensitivity of 81.2%, specificity of 88.9%, and positive and negative predictive accuracies of 53.8% and 96.7%, respectively. Conclusions: The logistic regression model generated in this study may be useful for screening for significant ARAS in patients undergoing transradial coronary angiography/intervention.

Key words: Renal artery stenosis, Transradial coronary angiography, Resistant hypertension
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1 Introduction

It is increasingly recognized that atherosclerotic renal artery stenosis (ARAS), accounting for about 90% of cases of renal artery stenosis (Safian and Textor, 2001), is an important cause of renal insufficiency, refractory hypertension, and cardiac destabilization syndromes (unstable angina and flash pulmonary edema) (Hackam *et al*., 2007; Dubel and Murphy, 2008). Significant ARAS, defined as no less than 70% luminal diameter narrowing (Rundback *et al*., 2002), is detected in 10%–20% of patients undergoing coronary angiography (White and Olin, 2009), a figure which increases to 20%–30% in high-risk populations (e.g., elderly patients with known atherosclerotic vascular disease) (Weber-Mzell *et al*., 2002). The mortality risk depends highly

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on the severity of ARAS. Since ARAS is a progressive disease associated with a loss of control of hypertension, and progression of ARAS to occlusion can occur at a rate of 10%–20% each year (Safian and Textor, 2001), early detection of significant ARAS is particularly important with respect to blood pressure control, prevention of renal insufficiency, and even improving survival. Clinical indications of significant ARAS should prompt the clinician to carry out further diagnostic testing. Invasive renal angiography is recommended when clinical suspicion is high and noninvasive testing is inconclusive or inconsistent with the clinical evidence (Hirsch *et al*., 2006). Some experts have recommended selective renal angiography at the time of coronary angiography in patients who are at increased risk of ARAS (Slovut, 2009). With a transfemoral approach, this is easily accomplished by simply pulling the right coronary artery angiographic catheter to the abdominal aorta and inserting it into the renal artery orifice. Currently, a transradial approach has been adopted as the routine arterial access of choice during percutaneous coronary intervention (PCI) (Brueck *et al*., 2009) because of its advantages of low bleeding complications and high patient compliance (Yip *et al*., 2009). However, renal angiography is not routinely performed through a transradial approach due to anatomical and technical difficulties, which may lead to misdiagnosis of significant ARAS. Screening of high-risk patients with ARAS before cardiac catheterization is essential for cardiovascular interventionists to select the optimal vascular access and catheter device (Slovut, 2009). In this study, we sought to develop a logistic regression model for screening for significant ARAS in patients who received coronary angiography through a transfemoral approach. To test its predictive accuracy, we prospectively applied the generated model to an additional 495 patients undergoing transradial coronary and renal angiography.

2 Materials and methods

2.1 Study design and patient population

This study consisted of two parts. Part 1 included 1813 patients who underwent selective coronary and renal angiography through a femoral approach between January 2006 and December 2009. Data on patient demographics, clinical and angiographic features, and biochemical measurements were collected retrospectively from the database of the Shanghai Ruijin Hospital PCI Outcomes Program (Lu *et al*., 2008). For the purpose of the study, patients with typical angiographic features suggestive of fibromuscular dysplasia (Lassiter, 1998) and those with glomerulonephritis or nephrotic syndrome were excluded. We also excluded those with moderate renal artery stenosis as these lesions are unlikely to cause hemodynamic compromise (van Jaarsveld *et al*., 2000) and are usually not indicated for revascularization (Jokhi *et al*., 2009; White and Olin, 2009). A logistic regression model for detecting the presence of significant ARAS was generated based upon clinical and angiographic features and biochemical measurements. Part 2 comprised 495 patients undergoing transradial coronary and renal angiography from July 2010 to October 2011. The logistic regression model generated in Part 1 was applied to these patients to test its predictive accuracy for detecting significant ARAS.

The protocol was approved by the hospital ethics committee and written informed consent was obtained from all patients.

2.2 Definitions

The diagnosis of type 2 diabetes was made according to the criteria of the American Diabetes Association, including symptoms of diabetes plus a casual plasma glucose concentration beyond 200 mg/dl (11.1 mmol/L), or an increased fasting (126 mg/dl (7.0 mmol/L)) or 2-h postprandial glucose (PG) level (200 mg/dl (11.1 mmol/L) during an oral glucose tolerance test) (Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, 2003), or the taking of oral hypoglycemic drugs or parental insulin medication. Hypertension was defined as systolic blood pressure ≥140 mmHg and/or diastolic blood pressure ≥90 mmHg. Resistant hypertension was defined as uncontrolled blood pressure despite using at least three antihypertensive medications in effective doses, ideally including a diuretic (Calhoun *et al*., 2008). Hyperlipidemia was diagnosed according to the guidelines of the National Cholesterol Education Program (Adult Treatment Panel (ATP) III) (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001). Multivessel coronary disease

was defined as the presence of ≥70% luminal diameter stenosis involving at least two major epicardial coronary arteries.

2.3 Coronary and renal angiography/stenting

Coronary angiography was performed using the standard Judkins technique through a femoral or radial artery approach (Innova 2000 or 2100 system, GE, USA). Selective renal angiography was carried out immediately after completion of coronary angiography. With a femoral approach, this was completed simply by pulling the right coronary angiographic catheter to the abdominal aorta and inserting it into the renal artery orifice. When radial access was used, a 6F right coronary artery angiographic catheter 125 cm in length was manipulated to engage the renal artery orifice.

Coronary and renal artery stenting was performed as described previously (Wheatley *et al*., 2009; Zhang *et al*., 2009; Yan *et al*., 2010). We often used a 6F multi-purpose guiding catheter 125 cm in length for renal artery stenting via radial arterial access.

2.4 Biochemical measurements

A blood sample was collected from each patient on the day of angiography after overnight fasting. Serum glucose, blood urea nitrogen, creatinine, uric acid, total cholesterol, low-density lipoprotein-cholesterol (LDL-C), high-density lipoprotein-cholesterol (HDL-C), lipoprotein (a), triglycerides, and apoprotein (Apo)-A and Apo-B were measured using standard methods (HITACHI 912 Analyser, Roche Diagnostics, Germany). Renal function was evaluated by the estimated creatinine clearance (Ccr) method derived from the Cockroft-Gault formula (Cockcroft and Gault, 1976), where Ccr (ml/min)= ([140−age]×weight (kg))/72×serum creatinine (mg/dl) (×0.85 if female). This equation is closely correlated with measured Ccr and provides a more accurate assessment of renal function than serum creatinine alone (Guimarães *et al*., 2007).

2.5 Statistical analyses

Data are presented as frequencies or percentages for categorical variables and means±standard deviation (SD) for continuous variables. Differences between groups were assessed using the χ^2 and unpaired *t*-tests. Multivariate logistic regression analysis was performed to assess the association of clinical characteristics, laboratory measurements, and angiographic features with significant ARAS. Because hypertension is quite common in coronary artery disease patients, resistant hypertension was considered as an independent variable for improving the value of the screening test. Variables that presented a level of statistical significance of <0.05 in the univariate analyses were chosen to generate the logistic regression model, and a receiver-operating characteristic (ROC) curve was calculated to determine the performance of the logistic regression model for detecting significant ARAS. To assess model calibration (or how closely the predicted probabilities reflect actual risk), the Hosmer-Lemeshow χ^2 statistic was computed. Finally, the logistic regression model generated was prospectively applied to an additional 495 patients to test its predictive value for significant ARAS. All tests were carried out with the level of significance set at $P<0.05$, considering the 95% confidence interval (CI). SPSS 16.0 software (SPSS, Chicago, Illinois, USA) was used for all statistical testing.

3 Results

3.1 Baseline clinical characteristics and results of biochemical measurements

Among the 1813 patients included in Part 1, 328 had significant ARAS and 1485 had normal renal arteries or non-significant ARAS. Patients with significant ARAS were older and had more resistant hypertension, type 2 diabetes, and multivessel coronary disease than those without. Serum levels of fasting glucose, creatinine, and blood urea nitrogen were higher, and Ccr was lower in patients with significant ARAS. Renal artery stenting was performed in 57.3% of patients with significant ARAS (Table 1).

3.2 Multivariate logistic regression analysis

Multivariate regression analysis revealed that after adjusting for confounding factors, resistant hypertension, older age (≥65 years), Ccr≤60 ml/min, type 2 diabetes, and multivessel coronary disease were independent factors for significant ARAS (Fig. 1). A logistic regression model for

Table 1 Clinical characteristics and angiographic findings

Variable	Normal or non-significant ARAS*	Significant ARAS**	*P*-value
Male	1157 (77.9%)	249 (75.9%)	NS
Age (year)	63.8±10.5	70.7±9.6	<0.001
Patients with cigarette smoking	387 (26.1%)	96 (29.3%)	NS
Patients with resistant hypertension	175 (11.8%)	169 (51.5%)	<0.001
Systolic blood pressure (mmHg)	123±17	168±20	<0.001
Diastolic blood pressure (mmHg)	76±10	100±13	<0.001
Patients with hyperlipidemia	809 (54.5%)	191 (58.2%)	NS
Total cholesterol (mmol/L)	4.3±0.92	4.4±1.05	NS
HDL-C (mmol/L)	1.03±0.25	1.05±0.28	NS
LDL-C (mmol/L)	2.58±0.73	2.62±0.91	NS
Triglyceride (mmol/L)	1.71±0.91	1.73±0.99	NS
Lipoprotein (a) (g/L)	0.25±0.20	0.28±0.21	NS
Apoprotein A (g/L)	1.13±0.11	1.17±0.12	NS
Apoprotein B (g/L)	0.88±0.23	0.92±0.25	NS
Patients with diabetes mellitus	258 (17.4%)	75 (22.9%)	0.022
Glucose (mmol/L)	5.7±1.4	7.1±1.5	<0.001
Urea acid (μmol/L)	337±91	341±98	NS
Blood urea nitrogen (mmol/L)	5.6±1.7	8.9±2.2	<0.001
Creatinine (μmol/L)	85±20	158±25	<0.001
Creatinine clearance (ml/min)	95±16	68±17	<0.001
Patient with 0-vessel disease	805 (54.2%)	53 (16.2%)	<0.001
Patient with 1-vessel disease	332 (22.4%)	65 (19.8%)	NS
Patient with 2-vessel disease	243 (16.4%)	101 (30.8%)	<0.001
Patient with 3-vessel disease	105 (7.1%)	109 (33.2%)	<0.001
Coronary stenting	680 (45.8%)	275 (83.8%)	<0.001
Renal artery stenting		188 (57.3%)	

ARAS: atherosclerotic renal artery stenosis; HDL-C: high-density lipoprotein cholesterol; LDL-C: low-density lipoprotein cholesterol; NS: not significant. Data are expressed as mean±SD or *n* (%); * total *n*=1 485; ** total *n*=328

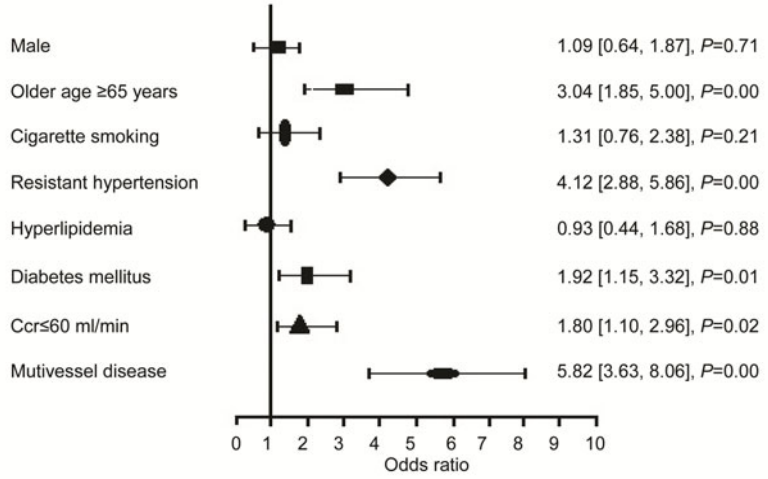

Fig. 1 Odds ratios of relative risks of variables for significant atherosclerotic renal artery stenosis (ARAS)

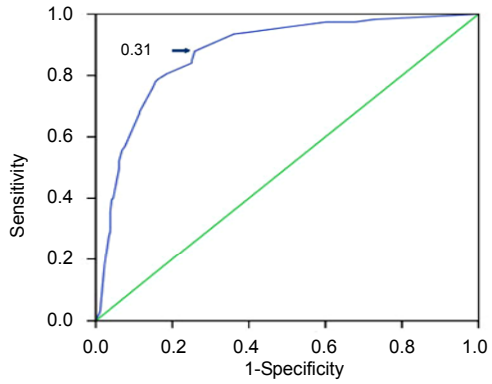

Fig. 2 Receiver-operating characteristic curve (ROC) of the logistic regression model for detecting significant atherosclerotic renal artery stenosis (ARAS)

detecting significant ARAS was generated as: $P/(1-P)$=exp(−2.618+1.112[age≥65 years]+1.891[resistant hypertension]+0.453[type 2 diabetes]+0.587[Ccr≤60 ml/min]+2.254[multivessel coronary disease]). The probability for each patient was calculated using the equation: $P=e^y/(1+e^y)$, where $y=\ln[P/(1-P)]$. The Nagelkerke R^2 value was 0.51, suggesting that the model explained 51% of the variation in the dependent variable. The Hosmer-Lemeshow χ^2 statistic demonstrated an adequate model fit (calibration 0.44). Receiver-operating characteristic curve analysis showed that the area under the curve (AUC) of the logistic regression model was 0.877 (95% CI, 0.845–0.908) with an optimal cut-off point of 0.31 for detecting ARAS (sensitivity 87.8%, specificity 74.1%) (Fig. 2).

3.3 Predictive value of logistic regression model

When the above logistic regression model was applied to an additional 495 patients undergoing transradial coronary and renal angiography, 56 out of 69 patients with significant ARAS were correctly identified, and 48 out of 426 patients without significant ARAS were falsely diagnosed, resulting in a sensitivity of 81.2%, specificity of 88.9%, and positive and negative predictive accuracies of 53.8% and 96.7%, respectively. Renal artery stenting was performed in 45 patients with significant ARAS through radial (n=37) or femoral (n=8) approaches.

4 Discussion

Significant ARAS has been increasingly recognized as a multiterritory (systemic) disease (Safian and Textor, 2001; Hirsch *et al*., 2006; Paraskevas *et al*., 2008). It causes ischemia-induced renal atrophy and nephron loss and activates the rennin-angiotensin-aldosterone system, leading to resistant hypertension, renal insufficiency or flash pulmonary edema, and may even reduce survival (Hackam *et al*., 2007; Dubel and Murphy, 2008). Screening for significant ARAS is crucial for preventing cardio-renal events and improving clinical outcomes because renal artery stenting can ameliorate blood pressure control and kidney function in carefully selected patients with significant ARAS (Sapoval *et al*., 2010). Consistent with previous reports (Paraskevas *et al*., 2008), we observed that after adjusting for possible confounding factors, resistant hypertension, older age (≥65 years), Ccr≤60 ml/min, type 2 diabetes, and multivessel coronary disease were independent factors for significant ARAS, while dyslipidemia and smoking had no predictive values. The present study suggests that conventional cardiovascular risk factors alone are not sensitive or specific enough to predict significant ARAS. In contrast, when a logistic regression model which incorporates multiple clinical, biochemical, and angiographic features was applied, the screening efficiency is significantly improved. The logistic regression model generated could prospectively detect significant ARAS in patients undergoing transradial coronary and renal angiography with reasonable sensitivity, specificity, and positive and negative predictive accuracies.

Doppler-ultrasound coupled with gadolinium-enhanced magnetic resonance imaging or computed tomography angiography have proven adequate for detecting significant ARAS in most patients, but these tests are expensive and require injection of large volumes of contrast media (Li *et al*., 2010; Solomon and Dauerman, 2010). Selective renal angiography at the time of coronary angiography through a femoral approach was thought to be cost-effective for the diagnosis of ARAS (van Helvoort-Postulart *et al*., 2007), as it is accomplished within a few minutes by simply pulling the right coronary angiographic catheter to the abdominal aorta and inserting it into

the renal artery orifice and requires only small amounts of contrast media (Ghaffari *et al*., 2009). Currently, a transradial approach is gaining increased acceptance for coronary angiography/intervention due to reduced access site complications and improved patient compliance (Rao *et al*., 2010). However, physicians are often reluctant to perform renal angiography during transradial coronary angiography/intervention because of anatomical considerations and technical difficulties, leading to misdiagnosis of significant ARAS. In these circumstances, identification of high-risk patients with significant ARAS is important. Our results suggest that for patients undergoing coronary angiography/intervention, who have a calculated probability value beyond the cut-off point (0.31), a transfemoral approach may be advised. Alternatively, renal angiography could proceed with a longer angiographic catheter during the index transradial coronary procedure, to avoid misdiagnosis of significant ARAS. Furthermore, our study shows that renal artery intervention could be accomplished successfully via radial arterial access. In this case, the technique of stent implantation was generally similar to that of a transfemoral approach except that a longer multipurpose guiding catheter was used (Shiraishi *et al*., 2005).

In conclusion, this study demonstrates that older age (≥65 years), resistant hypertension, type 2 diabetes, multivessel coronary disease, and reduced renal function (Ccr≤60 ml/min) are independent factors for significant ARAS. The logistic regression model incorporating clinical and biochemical factors and coronary angiographic findings may be useful in screening for significant ARAS, which could help cardiovascular interventionists to select an optimal vascular access site and treatment strategy (transradial renal angiography) before and during coronary angiography/intervention.

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