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Original Article

Long term prognosis of acute coronary syndrome with chronic renal dysfunction treated in different therapy units at department of cardiology: a retrospective cohort study

Cong Fu[1], Zulong Sheng[1], Yuyu Yao[1], Xin Wang[1], Chaojun Yu[2], Genshan Ma[1]

[1]*Department of Cardiology, Zhong Da Hospital Affiliated to Southeast University, Nanjing, Jiangsu, China;* [2]*Department of Cardiology, Jiang Yin Peoples' Hospital, Jiang Yin, Jiangsu, China*

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Abstract: Coronary care unit is common in hospitals and clinical centers which offer intensive care and therapy for severe coronary artery disease patients. However, if coronary care unit could improve the long term prognosis of acute coronary syndrome patients with renal dysfunction remain unknown. Accordingly, we designed this study to evaluate the differences of incidence of major adverse cardiovascular events for acute coronary syndromes patients with renal dysfunction who treated in coronary care unit or normal unit. The primary end point was all cause mortality. A total of 414 acute coronary syndromes patients with renal dysfunction involved in the study. The results showed that during 12-48 months follow-up, death of any cause occurred in 1.8% patients (4 of 247) in coronary care unit group, as compared with 1.8% in the normal group (3 of 167) (hazard ratio, 1.098; 95% confidence interval, 0.246 to 4.904; P=0.903). Kaplan-Meier survival analysis showed that there were no significant differences between the two groups with respect to the risk of death (P=0.903), revascularization (P=0.948), stroke (P=0.542), heart failure (P=0.198). This trial firstly revealed that acute coronary syndromes patients with renal dysfunction treated in coronary care unit and normal units. Our study showed that acute coronary syndromes patients with renal dysfunction treated in coronary care unit obtained no significant benefits compared with patients in normal units, although there was a declining tendency of the risk of major adverse cardiovascular effectswith patients in coronary care unit.

Keywords: Acute coronary syndrome, chronic renal dysfunction, coronary care units, outcomes

Introduction

Acute coronary syndrome (ACS) is a major health problem in the globe and China [1]. The prevalence of chronic kidney disease (CKD) is growing, and currently more than 10% of the population is affected in China [2]. Subjects with CKD and ACS have an increased risk of mortality and rate of major adverse cardiovascular events (MACEs) [3-9].

Patients with ACS and chronic renal dysfunction were common in clinical practice. The standard drug usage of ACS patients with chronic renal dysfunction was not satisfied due to high oxidative stress and hypercoagulability, whichdirectly leads to poor prognosis of ACS patients with renal dysfunction. Consequently, numerous hospitals and clinical centers have to establish the coronary care unit (CCU). Most of CCU have complete vital sigh monitoring including electrocardiogram (ECG), respiration, blood pressure, oxygen saturation and even invasive central venous catheter and Swan-Ganz float catheter to monitor heart function. Either, invasive hemodynamics parameter measurement was not applied to all CCU departments. CCU may also help the doctor to manager disease condition timlely so that the therapy plan was instituted individually. However, it is remaining unknown that if CCU could reduce the mortality and rate of MACEs of ACS patients with renal dysfunction.

Consequently, it is important to identify if CCU could improve clinical benefits for ACS patients with renal dysfunction. It is vital for clinical center and physicians to determine the probability of survival and evaluated the prognosis of subjects and saving medical sources. In consider-

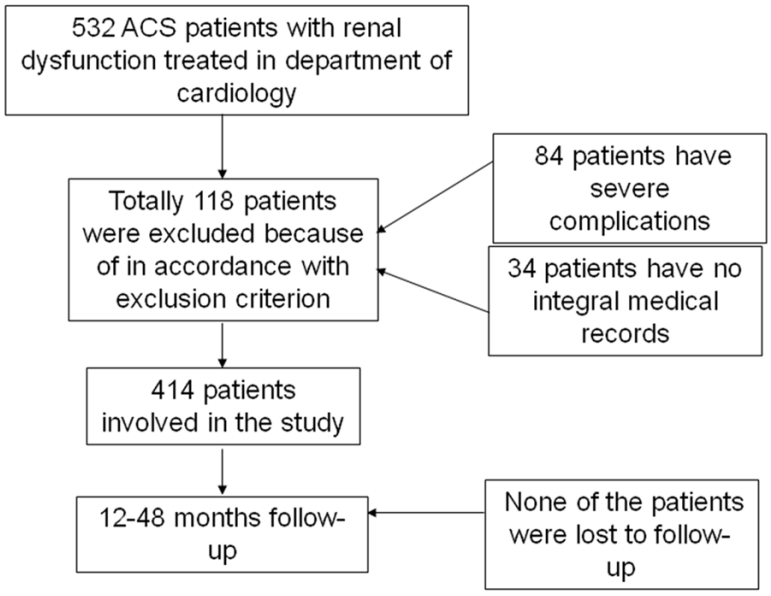

Figure 1. The flow diagram of this study.

ation of these reasons, we examined 414 ACS patients with renal dysfunction that treated in CCU or normal care unit. Clinical characters and follow-up data were collected so as to determine whether ACS patients with renal dysfunction could benefit from CCU therapy.

Methods

Study design

The study was a single center, retrospectively cohort study. Trial administration, data management, and statistical analyses were performed at the department of Cardiology, Zhong Da hospital affiliated to Southeast University. The patients' samples participated in this study that diagnosed as ACS with renal dysfunction was analyzed except for the patients who were in accordance with exclusion criterion. This trial design was approved by the Ethics Committee in Zhong Da hospital.

Patients' population

A total of 532 patients with ACS and chronic renal dysfunction diagnosed by coronary angiography (CAG) in department of Cardiology, Zhong Da hospital from December, 2009 to December, 2011. Glomerulonephritis was diagnosed by biochemical data and/or renal biopsy. Estimate glomerular filtration rate (eGFR) was calculated by MDRD formula. Chronic renal failure (CRF) was defined as the eGFR <90 mL/min/1.73 m^2. The patients were separated into two groups according to the care unit: CCU group and normal group. The definition of myocardial infarction was described previously [9]. Patients who have cancer, stroke, old myocardial infarction, received stents implantation before, severe liver dysfunction, heart failure, autoimmune diseases, infection diseases, receiving hormone, immunosuppressant therapy and hemodialysis, died before discharge from hospital were excluded. Either, lack of clinical document was excluded. Patients received drug therapy according to the situation of disease based on the guideline. All patients were asked to confirm their agreement to accept the 12-48 months follow-up by providing written informed consent.

Therapy procedures

All the patients that participated in the study underwent coronary angiography and 285 patients underwent percutaneous coronary intervention (PCI). Usage of platelet inhibitors or anticoagulants and other symptomatic treatment was left to the discretion of the treating physician according to guideline and clinical condition. For patients diagnosed as myocardial infarction, clopidogrel and aspirin were administered as 600 mg and 300 mg once arrived at the hospital and then immediately transferred to catheter room that CAG and/or PCI were performed. Clopidogrel and aspirin was administered 75 mg and 100 mg per day after PCI, respectively. Beta receptor blocker, statin and LMWH were administered according to the patients' status and guideline. Angiotensin converting enzyme inhibitors/angiotensin receptor blocker (ACEI/ARB) was administered in patients who have serum creatinine level less than 256 umol/L. For patients who were treated in CCU, real time monitoring of heart rate, heart rhythm, blood pressure, respiration and finger plus oxygen saturation were applicated, however, invasive central venous pressure and pulmonary artery wedge pressure detection were not included. Point-of-care test-

Table 1. Baseline Characteristics of the ACS Patients with chronic renal dysfunction

	Patients (n=414)		P
	CCU (n=247)	Normal (n=167)	
Sex, M/F	174/73	130/37	0.095
Age, y	69.8±11.8	69.5±10.3	0.836
WBC	7.9±3.1	7.9±3.4	0.922
cTnI	9.9±1.4	9.0±1.8	0.692
TC	4.3±1.0	4.3±1.0	0.670
TG	1.4±0.9	1.3±0.7	0.319
LDL	2.7±0.8	2.7±0.9	0.698
HDL	1.1±0.3	1.1±0.3	0.837
eGFR	66±19	66±20	0.910
Smoking, n (%)	78 (31.6)	51 (30.5)	0.823
HP, n (%)	191 (77.3)	122 (73.1)	0.321
DM, n (%)	65 (26.3)	51 (30.5)	0.348
LM, n (%)	12 (4.9)	11 (6.6)	0.451
LAD, n (%)	167 (67.6)	114 (68.3)	0.889
LCX, n (%)	117 (47.4)	75 (44.9)	0.623
RCA, n (%)	130 (52.6)	90 (53.9)	0.801
PCI, n (%)	169 (68.4)	116 (69.5)	0.823
Aspirin, n (%)	236 (95.5)	161 (96.4)	0.665
Betaloc, n (%)	179 (72.5)	124 (74.3)	0.688
ACEI/ARB, n (%)	148 (59.9)	95 (56.9)	0.539
Statin, n (%)	221 (89.5)	155 (92.8)	0.248
LMWH, n (%)	146 (59.1)	107 (64.1)	0.310
Clopidogrel, n (%)	183 (74.1)	128 (76.6)	0.555

*CCU: Coronary care unit. WBC: White blood cell, $\times 10^9$/L. cTnI: Cardiac troponin I, ng/mL. TC: Total cholesterol, mmol/L. TG: Triglyceride, mmol/L. LDL: Low density lipoprotein, mmol/L. HDL: High density lipoprotein, mmol/L. eGFR: estimate glomerular filtration rate, mL/min/1.73 m^2. HP: Hypertension. DM: Diabetes mellitus. LM: Left Main Artery. LAD: Left anterior descending branch. LCX: Left Circumflex Artery. RCA: Right coronary artery. PCI: Percutaneous coronary intervention. ACEI/ARB: Angiotensin converting enzyme inhibitors/Angiotensin receptor blocker. LMWH: Low molecular weight heparins.

ing of myocardial injury biomarkers was also applied in CCU. For patients who were treated in normal units, the usage of bedside monitors was determined by physician based on the fluctuation of patient's condition.

End points

Major adverse cardiovascular events were recorded (MACEs). Death from any cause was defined as the primary end points which defined as death of cardiac causes or any death without another known cause. Coronary revascularization was defined as angioplasty or stenting or coronary artery bypass grafting. Stroke was defined as loss of neurologic function due to an ischemic or hemorrhagic event. Heart failure was defined as BNP which measured in Zhong Da hospital was at least one value above the 5* 99th percentile upper reference limit. MACEs were verified by hospital medical records and telephone. No missing data was generated during follow-up.

Statistical analysis

The data were analyzed using the statistical software package of SPSS (SPSS Inc., Chicago, IL, USA, Version 17.0). Numerical variables were expressed as mean ± standard deviation and categorical variables as percentages. Continuous variables between groups were compared by unpaired Student's t test. Categorical variables were compared by Chi-square test. Kaplan-meier survival analysis was performed. Hazard ratio (HR) and 95% confidence intervals (CI) were calculated by Cox proportional hazard model. Two-tailed *P* values <0.05 were considered significant.

Results

Study population

During the 532 patients that treated in department of cardiology, 118 patients were excluded because of in accordance with exclusion criterion. 34 patients have no integral medical records and 84 patients have severe complications described above. Among all the 414 patients involved in the study, none of them have progressed to uremia. There were 167 patients involved in normal group and 247 patients in CCU group, respectively (**Figure 1**). None of these patients have received maintenance hemodialysis and progressed to hemodialysis. The baseline clinical characters and biochemical data, lesion coronary artery, complications and therapy were listed in **Table 1**. None of the patients were lost to follow-up with respect to the end point.

Patients' therapy procedure

In the normal group, 161 patients in 167 (96.4%) underwent aspirin therapy as well as 128 patients (76.6%) underwent clopidogrel

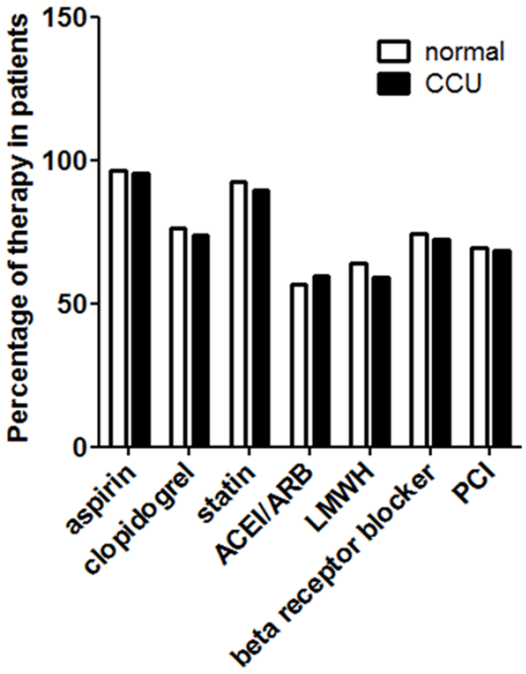

Figure 2. The status of drug and invasive therapy in patients involved in two groups.

therapy. 155 patients received statin therapy (92.8%) and 95 patients (56.9%) received ACEI/ARB therapy, respectively. 107 patients (64.1%) received low molecular weight heparins (LMWH) therapy. 124 patients (74.3%) received beta receptor blocker treatment. In addition, 116 patients (69.5%) received stent implantation and/or coronary balloon angioplasty. In the CCU group, 236 patients in 247 (95.5%) were treated by aspirin as wells as 183 patients (74.1%) received clopidogrel therapy. 221 patients (89.5%) received statin therapy and 148 patients (59.5%) received ACEI/ARB, respectively. 146 patients (59.1%) underwent LMWH therapy. 179 patients (72.5%) patients received beta receptor blocker treatment. 169 patients (68.4%) underwent stent implantation and/or coronary balloon angioplasty. No differences of drug and invasive treatment were detected between groups (**Figure 2**; **Table 1**).

Long term clinical outcomes

3 patients died during 12-48 (average 25 months) months follow-up in normal group compared with 4 patients died in CCU group (hazard ration [HR], 1.098; 95% confidence interval [95% CI], 0.246-4.904; P=0.903). 37 patients in normal group and 55 patients in CCU group have underwent revascularization, respectively (HR, 0.986; 95% CI, 0.650-1.496; P=0.948). Stroke occurred in 9 patients in normal group and 10 in CCU group, respectively (HR, 1.322; 95% CI, 0.537-3.253; P=0.544). Heart failure occurred in 24 patients in normal group and 25 in CCU group, respectively (HR, 1.149; 95% CI, 0.822-2.520; P=0.202) (**Table 2**). Kaplan-meier survival analysis showed that there were no difference of the cumulative hazard of all cause death (P=0.903), revascularization (P=0.948), stroke (P=0.542), heart failure (P=0.198) between two subgroups (**Figure 3**).

Subgroups analysis

Further, a subgroups analysis was performed according to renal function stratification. Three subgroups were specified as eGFR 65-90, 40-64 and 15-39 mL/min/1.73 m^2, respectively. The primary outcome of revascularization was consistent among all subgroups (**Table 3**). The data showed that there is no significant improvements in decreasing the ratio of revascularization in CCU no matter the grade of renal dysfunction.

Discussion

In this study, we find that ACS patients with renal dysfunction treated in CCU and normal unit exhibit a common long-term clinical outcome.

A significantly lesser usage of standard treatment of ACS in patients with chronic renal failure was comman in the clinical [10]. Many of drugs were reasonless for patients with renal dysfunction because of drugs metabolism may further impair renal function. In addition, intracellular high oxidative stress and hypercoagulable states may further affect life quality and increase mortality. Previous studies showed that eGFR was a independent prediction factor of MACEs even in patients without renal failure [11]. In CAD patients who underwent PCI, high mortality was revealed in those who were disgnosed with CKD no matter bare metal stent or drug elution stent was implanted [12]. For patients who have received coronary artery bypass graft, high mortality was either detected [13]. Furthermore, endothelial dysfunction and mitochondrial impairment occurred in patients with renal dysfunction may increase the incidence of stroke and hemorrhage and lead to progression of coronary lesion [14-17]. The usage of standard therapy recommended

Table 2. Hazard ratio of MACEs according to two groups

	Patients (n=414)			P
	CCU (n=247)	Normal (n=167)	HR (95% CI)	
Death				
No./total no. (%)	4/247 (1.6)	3/167 (1.8)	1.098 (0.246-4.904)	0.903
Revascularization				
No./total no. (%)	55/247 (22.3)	37/167 (22.2)	0.986 (0.650-1.496)	0.948
Stroke				
No./total no. (%)	10/247 (4.0)	9/167 (5.4)	1.322 (0.537-3.253)	0.544
Heart failure				
No./total no. (%)	25/247 (10.1)	24/167 (14.4)	1.149 (0.822-2.520)	0.202

HR was calculated as CCU group was control group. CCU: Coronary care unit. HR: Hazard ratio. CI: Confidence interval. no: Number.

by therapy guideline [18, 19] exhibit benefits for patients, but it is difficult to practice due to the reason stated above.

In our study, drug therapy and intervention strategy displayed no differences between normal and CCU groups. Real time vital monitoring was applied, however it lack of invasive hemodynamics measurement in CCU group, which showed little benefits to ACS patients with renal dysfunction. Although vital monitoring was a effective method which can timely monitor the vital sigh to change the therapy procedures according to the changing of diseases condition, especially for the patients of ACS who have high risk of death and complications. Previous studies showed that monitoring could more effectively apllied to early cardiovascular disease detection [20]. And electrocardio-monitoring have manifested the advantage in efficiently detecting fatal arrhythmia promptly, which could save patients from death. However, it lacks of clinical evidence to demonstrate if the vital monitoring could reduce the rate of death for ACS patients with CRF.

Invasive hemodynamic measurement is a widely used cardiac function monitor that can indicate the action of left heart and right heart especially for cardiac shock. Previous studies have reported that central venous pressure and pulmonary capillary wedge pressure measurement may have potential benefit for patients who underwent coronary artery by-pass [21]. For ACS patients, invasive measurement of hemodynamic may predict the response to volume administration in the setting of acute left ventricular myocardial infarction [22]. Our trial showed that in CCU patients with renal dysfunction, no significant clinical benefits were obtained, although long time cumulative hazard of MACEs was lower than patients treated in normal unit. These results have further proved that intensive care without invasive hemodynamic measurement for ACS patients with renal dysfunctin who underwent the same drug therapy failed to add benefits for patients. If invasive hemodynamic measurement couldimprove prognosis of ACS patients with renal dysfunction was still uncertain.

Point-of-care testing which applied in CCU provide a quick method to determine the serum myocardial injury biomarkers that can early identified myocardial infarction. In ACS with renal dysfunction patients, unbalanced blood coagulation and fibrinolysis may lead to insufficient usage of anti-platelets and anti-coagulation drugs. Point-of-care testing of myocardial injury biomarkers may further evaluated the damage of cardiac and condition of recovery. However, our data showed that there was no significant clinical benefits of point-of-care testingfor ACS patients with chronic renal dysfunction. Previous studies dispalyedthat point-of-care testing of creatinine and eGFR can detect renal impairment early and prevent contrast-induced nephropathy [23, 24], however, up to now, there were no definite evidences approved that point-of-care testing of myocardial injury could prevent prognosis of nephropathy. Our study first revealed that testing myocardial biomarker alone seemed bring patients limited benefits.

Standard drug therapy play the key role in CAD and ACS therapy, especially in patients complied with renal dysfunction. Reasonable usage of anti-platelets, anti-coagulation, lowing cholesterol and ACEI/ARB can definitely reduce the rate of death and improve life quality. Between the two groups, there were no no statistical differences therapy procedures include drug and invasive treatment ere. Although real time vital monitoring and point-of-care myocardial biomarkers testing were applied to patients treat-

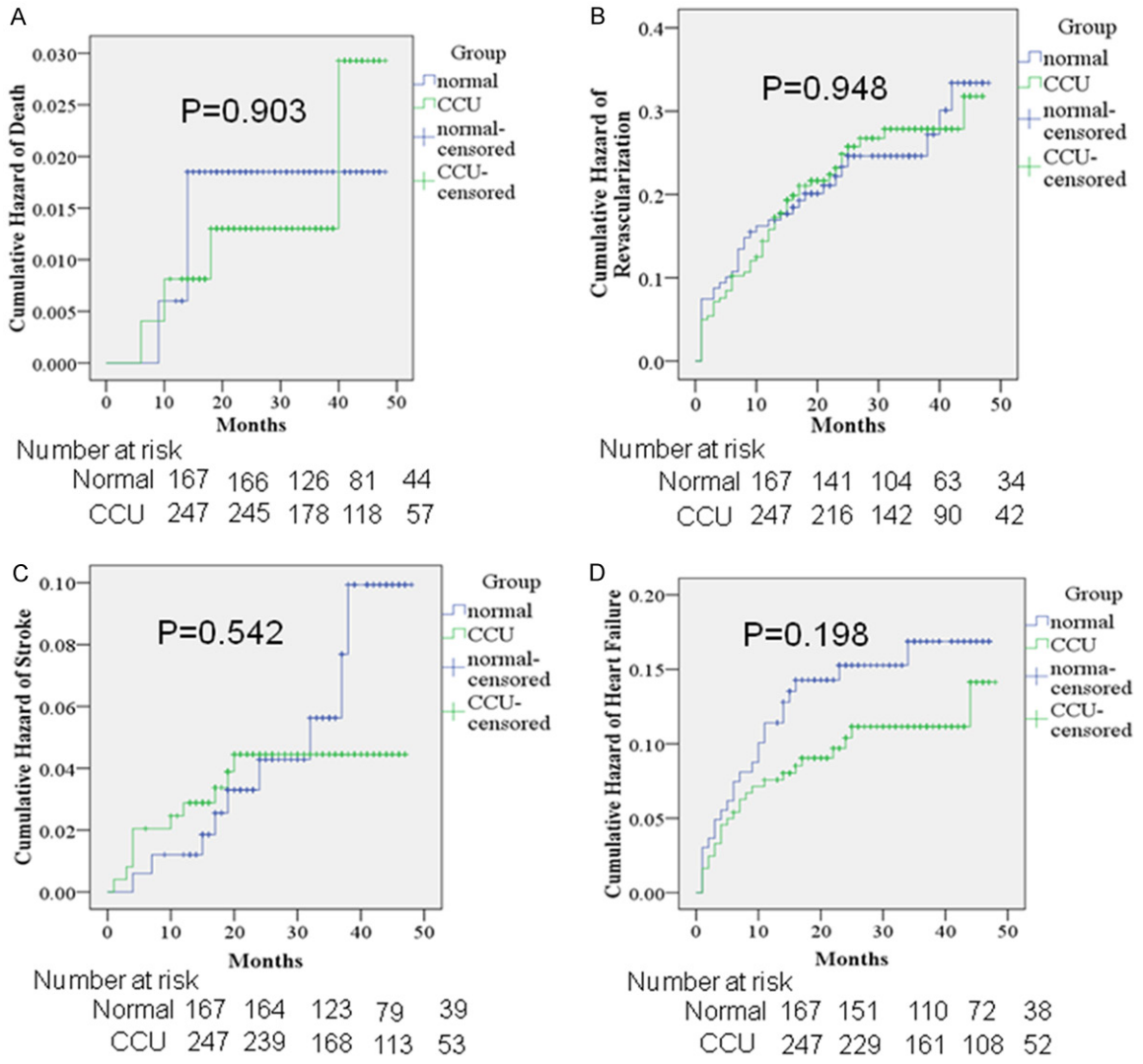

Figure 3. Kaplan-Meier survival analysis of MACEs. A. Cumulative hazard ratio of death between two groups. B. Cumulative hazard ratio of revasclarization between two groups. C. Cumulative hazard ratio of stroke between two groups. D. Cumulative hazard ratio of heart failure between two groups.

ed in CCU, similar usage of major drug lead to no significant benefits.

There are some obviously limitations in this study. The detailed drug therapy during follow-up was not collected in detail. Further, as a retrospective study, the sample sized was not accurately calculated.

Conclusion

ACS Patients with renal dysfunction treated in CCU showed lower incidence of MACEs. However, significantly differences were not observed. ACS patients with renal dysfunction obtained little clinical benefits from CCU.

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Disclosure of conflict of interest

None.

Address correspondence to: Drs. Genshan Ma and Yuyu Yao, Department of Cardiology, Zhong Da Hospital Affiliated to Southeast University, Ding-

Table 3. Hazard ratios for the revascularization in subgroups of patients

Subgroup	Normal	CCU	Hazard ratio (95% CI)	P
	No of events/total patients	No of events/total patients		
GFR (mL/min/1.73 m^2)				
≥65	25/100	40/156	0.973 (0.590-1.604)	0.916
40-64	9/48	11/63	1.103 (0.456-2.671)	0.828
15-39	3/19	4/28	1.033 (0.231-4.617)	0.966

HR was calculated as CCU group was control group. CCU: Coronary care unit. CI: Confidence interval. no: Number.

jiaqiao 87#, Nanjing, Jiangsu, China. Tel: +86 8326-2391; +86 25 8327 2038; E-mail: magenshan@hotmail.com (GSM); yaoyuyunj@hotmail.com (YYY)

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