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Original Article

Hospitalized mortality and vascular events in CKD patients after receiving percutaneous coronary intervention: a nationwide cohort study

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Abstract: Background: Cardiovascular disease is the crucial morbidity and mortality in patients with chronic kidney disease (CKD). However, clinical outcomes of mortality and vascular events in patients with CKD and end-stage renal disease (ESRD) on dialysis after receiving percutaneous coronary intervention (PCI) for cardiovascular disease have remained unclear in the literature, as compared with the general population. Our aim was to determine the post-PCI hospitalized mortality and vascular events in patients with CKD and ESRD in Taiwan. Methods: Using Taiwan National Health Institutes Research Database, we identified patients who received PCI from 2010-2011. Of a total of 2,273 patients without CKD, 297 patients with CKD, and 125 patients with ESRD on dialysis were enrolled in this study. Main outcomes were the post-PCI hospitalized mortality and vascular events. Results: There was higher post-PCI hospitalized mortality in patients with CKD and with ESRD-on-dialysis than in patients without CKD. Post-PCI vascular events in both patients with CKD and with ESRD on dialysis were significantly higher than those in patients without CKD [adjusted odds Ratio (OR) = 1.936; 95% CI, 1.085 to 4.407, $P = 0.026$, and adjusted OR = 6.220; 95% CI, 2.901 to 13.337, $P<0.001$, respectively]. Conclusion: We need to pay attention to the increased post-PCI hospitalized mortality and vascular events in patients with CKD and with ESRD on dialysis.

Keywords: Chronic kidney disease, dialysis, percutaneous coronary intervention, vascular events

Introduction

Cardiovascular disease is one of major morbidities in patients with chronic kidney disease (CKD) and end-stage renal disease (ESRD) [1, 2]. The complex risk of cardiovascular disease in these patients could be due to underlying diseases, anaemia, the activation of renin-angiotensin system, poor fluid homeostasis, bone mineral metabolism, toxic uraemic accumulation, and acidosis [3]. Percutaneous coronary intervention (PCI) provides excellent angiographic diagnosis and therapy for cardiovascular disease in patients with CKD and ESRD [2].

Recently reports indicated that the development of femoral pseudo-aneurysm following PCI is common in the general population [4]. However, the post-PCI outcomes in patients with CKD and ESRD have remained rarely reported, as compared with the general population. Thus, we used the NHI research database from 2010-2011 to examine the outcomes of post-PCI hospitalized mortality and vascular events in patients with kidney health, with CKD, and with ESRD on dialysis.

Subjects and methods

Data source

The data were analysed from the NHI research database, which is collected by the Taiwan National Health Research Institute (NHRI). The

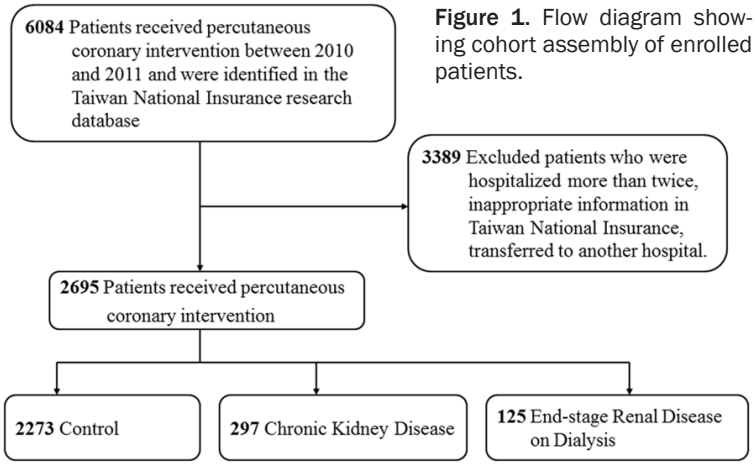

Figure 1. Flow diagram showing cohort assembly of enrolled patients.

NHI program has provided compulsory universal health insurance since 1995, and more than 99% of Taiwanese citizens have been enrolled. This database provides clinical data for population-based cohort investigations in Taiwan. The NHI research database is one of the highest quality databases of its kind in the world, and has been broadly used for longitudinal cohort studies, including our reports [5-8].

All data in the NHI research database are encrypted to protect the privacy of individuals. The data from the NHI database provide the patient identification number, sex, birth date, names of medical institutions where care was given, diagnostic codes according to the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM), prescription use, procedure codes, healthcare costs, dates of admission and discharge, date of death, outpatient and inpatient claims data, and related information. All datasets can be interlinked through each individual's unique identification number.

Study cohort and patient selection

This study received prior approval from the Ethics Committee and Human Subjects Institutional Review Board of Taipei Medical University (TMU-JIRB number: 201404035). All patients (*n* = 6,084) who received PCI from January 1, 2010 to December 31, 2011 were initially enrolled, as shown in **Figure 1**. Subjects (*n* = 3,389) were excluded if they had been hospitalized more than twice, had inappropriate information in Taiwan National Insurance, had been transferred to another hospital, and had missing data on identification numbers, birthday, sex, or death date. The resulting patients (*n* = 2,695) for whom follow-up data were available were assigned to three groups: patients without CKD (Control group, *n* = 2,273), patients with chronic kidney disease (CKD group, *n* = 297), and patients with ESRD on dialysis therapy (ESRD on Dialysis group, *n* = 125). The study of the follow-up period ranged from the time of receiving PCI to the time of the study endpoints, which were date of death or December 31, 2011.

Outcomes measures

The study endpoints were hospitalized mortality and vascular events following PCI. Vascular events were defined as vascular haematoma and pseudo-aneurysm. The ICD-9-CM diagnostic codes used were as follows: vascular haematoma (998.1) and pseudo-aneurysm (442.3).

Diagnostic and procedure codes

Diagnostic (ICD-9-CM) and procedure codes were interlinked with the patient identification numbers in the NHI research database. Survival time was calculated from the time of revascularization to the study endpoint. The ICD-9-CM diagnostic and procedure codes used were as follows: CKD (016.0, 095.4, 189.0, 189.9, 223.0, 236.91, 250.4 271.4, 274.1, 283.11, 403.x[1], 404.x[2] 404.x[3] 440.1, 442.1, 447.3, 572.4, 580, 581, 582, 583, 584, 585, 586, 587, 588, 591, 642.1, 646.2, 753.12, 753.13, 753.14, 753.15, 753.16, 753.17, 753.19, 753.2, 794.4), aneurysm excision (38.68), aneurysm repairs (39.52), PCI (36.01, 36.02, 36.04, 36.05, 36.06, 36.09), coronary angiography (37.22, 37.21, 37.23), coronary artery bypass grafting (CABG) (36.11, 36.12, 36.13, 36.14, 36.15, 36.16), and dialysis therapy (39.95, 54.98). The definition and analysis of the Charlson comorbidity index (CCI) in Supplementary Table 1 were derived from the methods by Charlson *et al*., [9]. which is commonly used to analyse the impacts of comorbidities on survival and clinical outcomes [10].

Table 1. Clinical characteristics in patients who received percutaneous coronary intervention

	Control (*n* = 2,273)		CKD (*n* = 297)		ESRD on Dialysis (*n* = 125)		*P value*
	n	%	*n*	%	*n*	%	
Sex							<0.001*
Male	1,575	69.3	188	63.3	63	50.4	
Female	698	30.7	109	36.7	62	49.6	
Age (years)[a]	64.0 ± 13.7		69.3 ± 11.5		65.9 ± 11.1		<0.001*
Age Group							<0.001*
≤Age 44	176	7.8	5	1.7	5	4	
Age 45-Age 54	372	16.4	29	9.8	17	13.6	
Age 55-Age 64	610	26.8	71	23.9	36	28.8	
Age 65-Age 74	596	26.2	82	27.6	36	28.8	
≥Age 75	519	22.8	110	37.0	31	24.8	
Total Scores of CCI[a]	0.9 ± 1.1		1.5 ± 1.7		1.7 ± 1.4		<0.001*
PCI Type							0.083
Diagnostic	1,093	48.1	125	42.1	53	42.4	
Therapeutic	1,180	51.9	172	57.9	72	57.6	

CKD = chronic kidney disease; CCI = Charlson comorbidity index; ESRD = end-stage renal disease; PCI = percutaneous coronary intervention. Control group: patients without CKD. [a]Average value ± standard deviation. *P<0.05.

Table 2. Clinical outcomes in the enrolled Patients after receiving percutaneous coronary intervention

	Control (*n* = 2,273)		CKD (*n* = 297)		ESRD on Dialysis (*n* = 125)		*P value*
	n	%	*n*	%	*n*	%	
Hospitalized mortality							0.008*
Survival	2,225	97.9	282	94.9	121	96.8	
Death	48	2.1	15	5.1	4	3.2	
Vascular events after PCI							0.001*
Yes	12	0.5	4	1.3	4	3.2	
No	2,261	99.5	293	98.7	121	96.8	
Hospitalized day[a]	11.2 ± 16.7		18.9 ± 28.4		16.8 ± 20.5		<0.001*
Medical costs (NTD)[a]	256,544.5 ± 264,233.5		337,224.9 ± 361,702.5		340,312.1 ± 311,266.8		<0.001*

CKD = chronic kidney disease; ESRD = end-stage renal disease; NTD = new Taiwan dollar; PCI = percutaneous coronary intervention. Control group: patients without CKD. [a]Average value ± standard deviation. *P<0.05.

Statistical analysis

Patient demographic data included sex, age, the CCI score and type of cardiac intervention. Age was entered as a categorical variable (≤ 44, 45-54, 55-64, 65-74, or ≥75 years). A chi-square test was used to compare differences in demographic characteristics of the groups. A multivariable logistic regression model was used to assess the impact of independent predictors on the adjusted Odds Ratio (OR) of hospitalized mortality and vascular events after receiving PCI adjusted by age, sex, CCI, PCI type, doctor's servicing amount, hospital's servicing amount, hospital levels, CABG, and hospitalized days. IBM SPSS Statistics (version 18) was used for the statistical analysis. All statistical tests were 2-sided, and a *P* value <0.05 was considered statistically significant for comparisons of subject characteristics.

Results

Patient characteristics

Table 1 presents the clinical and demographic characteristics of patients undergoing PCI procedures. We found significant differences among men in the healthy control and the CKD group. Average age of patients with kidney health was 64.0 ± 13.7 years, with CKD was 69.3 ± 11.5 years, and with ESRD on dialysis was

Table 3. Hospitalized mortality after receiving percutaneous coronary intervention in patients with different kidney functions by using multivariable logistic regression model

Variables	Adjusted OR	95% CI	*P value*
Control	Reference		
CKD	1.698	1.104-2.610	0.016*
ESRD on HD	1.245	1.008-2.423	0.021*
Gender			
Female	Reference		
Male	1.024	0.789-1.407	0.742
Age	1.038	1.010-1.052	<0.001*
CCI	1.212	1.007-1.225	<0.001*
PCI type			
Diagnostic	Reference		
Therapeutic	1.597	1.222-2.187	0.023*
Doctor's Servicing Amounts			
Low (1-25 cases/year)	Reference		
Medium (26-50 cases/year)	0.320	0.155-1.060	0.062
High (51-90 cases/year)	0.751	0.323-1.747	0.507
Hospital Levels			
District hospital	Reference		
Regional hospital	1.154	0.277-4.811	0.845
Medical center	0.827	0.197-3.477	0.796
CABG			
No	Reference		
Yes	2.388	1.074-5.311	0.033*
Vascular events			
No	Reference		
Yes	4.069	1.536-10.778	0.005*
Hospitalized Days	1.002	0.996-1.008	0.549

CKD = chronic kidney disease; CCI = Charlson comorbidity index; CABG = coronary artery bypass grafting; CI = confidence interval; ESRD = end-stage renal disease; PCI = percutaneous coronary intervention. Control group: patients without CKD. Adjusted Odds Ratio (OR) of hospitalized mortality and vascular events after receiving PCI adjusted by age, sex, CCI, PCI type, doctor's servicing amount, hospital's servicing amount, hospital levels, CABG, and hospitalized days. *P<0.05.

65.9 ± 11.1 years, reaching a statistically significant difference (P<0.001). Patients with chronic kidney disease or end-stage renal disease on dialysis had significantly higher CCI scores than the healthy controls.

Hospitalized mortality and vascular events after receiving PCI procedures

The results of the clinical outcomes, including hospitalized mortality and vascular events after receiving PCI procedures are showed in **Table 2**. For hospitalized mortality, there was 2.1% in patients with kidney health, 5.1% in patients with CKD, 3.2% in patients with ESRD on dialysis (P = 0.008). Vascular events had a 0.5% incidence in healthy controls, 1.3% in patients with CKD, and 3.2% in those with ESRD on dialysis, reaching a statistically significant difference (P = 0.001). In addition, both hospitalized days and medical costs significantly increased in patients with ESRD on dialysis as compared to healthy controls and the CKD group.

Table 3 displays the multivariable logistic regression data of hospitalized mortality in patients with kidney health, with CKD, and with ESRD on dialysis after receiving PCI procedures. Patients with CKD and ESRD on dialysis had a higher risk for hospitalized mortality relative to those in the healthy control [adjusted odds Ratio (OR) = 1.698; 95% CI, 1.104 to 2.610, P = 0.016, and adjusted OR = 1.245; 95% CI, 1.008 to 2.423, P = 0.021, respectively]. These patients with older age, higher CCI scores, receiving therapeutic PCI and CABG, and having vascular events had the significant impact on increased hospitalized mortality.

The results of the multivariable logistic regression model model for vascular events after receiving PCI in patients with kidney health, with CKD, and with ESRD on dialysis are presented in **Table 4**. Both patients with CKD and ESRD-on-dialysis had higher risks of vascular events [adjusted OR = 1.936; 95% CI, 1.085 to 4.407, P = 0.026, and adjusted OR = 6.220; 95% CI, 2.901 to 13.337, P<0.001, respectively], compared with healthy controls.

Discussion

Using the Taiwan NHI research database, this study investigated the comparative outcomes of hospitalized mortality and vascular events after receiving PCI in patients with kidney

Table 4. Multivariable logistic regression model for the risk of vascular events in the enrolled patients after receiving percutaneous coronary intervention

Variables	Vascular events		
	Adjusted OR	95% CI	*P value*
Control	Reference		
CKD	1.936	1.085-4.407	0.026*
ESRD on Dialysis	6.220	2.901-13.337	<0.001*
Sex			
Female	Reference		
Male	0.821	0.287-1.946	0.321
Age	1.012	0.987-1.037	0.357
CCI	1.491	1.334-1.722	<0.001*
PCI type			
Diagnostic	Reference		
Therapeutic	2.513	1.257-5.021	0.009*
Doctor's servicing amounts			
Low (1-25 cases/year)	Reference		
Medium (26-50 cases/year)	0.488	0.198-1.206	0.120
High (51-90 cases/year)	0.897	0.466-2.797	0.311
Hospital Levels			
District hospital	Reference		
Regional hospital	1.116	0.164-2.614	0.746
Medical centre	1.124	0.112-2.782	0.694
CABG			
No	Reference		
Yes	3.353	1.133-9.927	0.029*
Hospitalized Days	1.010	1.003-1.018	0.007*

CKD = chronic kidney disease; CCI = Charlson comorbidity index; CABG = coronary artery bypass grafting; CI = confidence interval; ESRD = end-stage renal disease; PCI = percutaneous coronary intervention. Control group: patients without CKD. Adjusted Odds Ratio (OR) of hospitalized mortality and vascular events after receiving PCI adjusted by age, sex, CCI, PCI type, doctor's servicing amount, hospital's servicing amount, hospital levels, CABG, and hospitalized days. *P<0.05.

health, with CKD, and with ESRD on dialysis. After multivariate adjustments, the major findings of our study were that: (1) As compared with patients with kidney health, patients with CKD and ESRD on dialysis had increased hospitalized mortality following PCI; and (2) As relative to patients with kidney health, patients with CKD and ESRD on dialysis had higher risks of vascular events after PCI procedures.

Hospitalized mortality in patients with CKD and with ESRD on dialysis has been rarely clarified after PCI procedures, as compared with the general population. Our data showed that higher risk of hospitalized mortality in patients with CKD and with ESRD on dialysis than in healthy control following PCI procedures, which are consistent with the report of *Vasu et al.* that advanced CKD (stage 3-5) raised higher risk of hospitalized mortality than patients without advanced CKD (adjusted OR = 2.4; 95% CI, 1.002 to 5.804, P = 0.049) [11]. Hospitalized mortality in patients with CKD and ESRD on dialysis could be derived from risks of coronary artery calcification and cardiovascular mortality [12, 13].

In our study, the analysis showed that raised risks of vascular events were related to worsening renal function. Additionally, Badr *et al.* presented that patients with post-PCI femoral pseudoaneurysm were older and had higher comorbidities of diabetes and CKD [4]. There was an inverse relationship between creatinine clearance and the rate of vascular events [14]. Thus, our data further demonstrated that patients with CKD and ESRD on dialysis had significantly higher risk of vascular events than patients with kidney health.

The existence of CKD and ESRD leads to the development of vascular events following PCI procedures. The pathophysiology and course of vascular events differ in the presence of CKD and ESRD, such as with advanced atherosclerosis superimposed on arterial calcification, which easily causes vascular stiffness and rupture [15]. These phenomena are because of comorbidities (such as hypertension, diabetes, hyperlipidaemia), uraemic toxins, chronic inflammations, and abnormal deposition of calcium and phosphorus, which increase the development of atherosclerosis and even calcification of the arteries [16-18]. In this study, we also observed that higher CCI scores and having CABG surgery have a significant impact on increasing the risk of vascular events after PCI procedures in patients with CKD and with ESRD on dialysis.

The main strength of our study is that the Taiwan NHI research database is one of the

largest and nationally reliable databases of its kind that has been broadly used for longitudinal cohort studies, including our previous reports [5-8]. This study has some limitations. The NHI research database protects subjects' privacy, so we were unable to obtain information about body weight, educational levels, personal activity, and family history. Second, the causes of death could not be obtained to further analyse.

Conclusion

Our analysis of the Taiwan NHI research database indicated that patients with CKD and ESRD on dialysis had increased hospitalized mortality after undergoing PCI, as compared with patients with kidney health. Moreover, patients with CKD and ESRD on dialysis had the higher risks of vascular events than patients with kidney health. Thus, it is mandatory to pay attention to post-PCI vascular events in patients with CKD and ESRD on dialysis.

Disclosure of conflict of interest

None.

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Supplementary Table 1. Charlson Comorbidity Index

Comorbid conditions	ICD-9-CM	Weights
Myocardial infarction	410-410.9, 412	1
Congestive heart failure	428-428.9	1
Peripheral vascular disease	443.9, 441-441.9, 785.4, V43.4	1
Cerebrovascular disease	430-437 (only 438 in index admission)	1
Rheumatic disease	710.0, 710.1, 710.4, 714.0-714.2, 714.81, 725	1
Peptic ulcer disease	531-534.9	1
Hemiplegia or paraplegia	344.1, 342-342.9	2
Dementia	290-290.9	1
Chronic pulmonary disease	490-496, 505-505, 506.4	1
Renal disease	582-582.9, 583-583.7, 585, 586, 588-588.9	2
Any malignancy	140-172.9, 174-195.8	2
Leukaemia	203-208.9	2
Lymphoma	200-202	2
Metastatic solid tumour	196-199.1	6
Mild liver disease	571.2, 571.4-571.49, 571.5, 571.6	1
Moderate or severe liver disease	456-456.21, 572.2-572.8	3
Diabetes	250-250.3, 250.7	1
Diabetes with chronic complication	250.4-250.6	2
AIDS	042	6
Age group		
0-49 years		0
50-59 years		1
60-69 years		2
70-79 years		3
80-89 years		4
90-99 years		5

Score defined as the sum of the patient's disease and age weights.