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Title:
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Date:
2021-05-01

Citation:
Bloom, J. E., Dinh, D. T., Noaman, S., Martin, C., Lim, M., Batchelor, R., Zheng, W., Reid, C., Brennan, A., Lefkovits, J., Cox, N., Duffy, S. J. & Chan, W. (2021). Adverse impact of chronic kidney disease on clinical outcomes following percutaneous coronary intervention. Catheterization and Cardiovascular Interventions, 97 (6), pp.E801-E809. https://doi.org/10.1002/ccd.29436.

Persistent Link:
https://hdl.handle.net/11343/276751

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Adverse Impact Of Chronic Kidney Disease On Clinical Outcome Coronary Intervention

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Running title: Renal Impairment Predicts Poor Outcomes in PCI

Funding: The Victorian Cardiac Outcomes Registry (VCOR) was original Victorian Department of Health in 2011 and a one-off grant from Mediba funded by the Department of Health and Human Services, Victoria with i University

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The authors have no conflicts of interest to declare.

Total word count: 4,733

Aims:

We aimed to assess the impact of the severity of CKD with long-term o undergoing percutaneous coronary intervention (PCI).

Methods:

We analysed data on consecutive patients undergoing PCI enrolled in the Registry (VCOR) from January 2014 to December 2018. Patients were s function; eGFR ≥60, 30-59 and <30 mL/min/1.73m^2 (including dialysis) long-term all-cause mortality obtained from linkage with the Australian N The secondary endpoint was a composite of 30-day major adverse cardiac (MACCE).

Results:

We identified a total of 51,480 patients (eGFR ≥60, n=40,534; eGFR 3 n=1,425). Compared with patients whose eGFR was ≥60, those with eGF on average older (77 and 78 vs 63 years) and had a greater burden of Worsening CKD severity was independently associated with greater adju mortality: eGFR<30 hazard ratio (HR) 4.21 [CI 3.7-4.8] and eGFR 30 compared to eGFR ≥60, all p<0.001.

Conclusion:

In this large, multicentre PCI registry, severity of CKD was associated wi

Abbreviations: Chronic kidney disease (CKD), Percutaneous corona

Elevation Myocardial Infarction (STEMI), Non ST-Elevation Myocardia

National Death Index (NDI).

Introduction:

Chronic kidney disease (CKD) is a well-established independent risk fa coronary artery disease (1–4). Among patients with CKD, cardiovascular cause of morbidity and mortality after adjustment for traditional cardiovas diabetes and hypertension (5,6). In this context, 30-40% of patients pr revascularization procedures have pre-existing renal impairment(1–4). De dysfunction in those presenting for coronary angiography, patient's w excluded or significantly under-represented in major clinical outcome studi of revascularization and medical therapy for ischaemic heart disease(5- performed a systematic review which demonstrated that three-quarters of excluded patients with greater than moderate CKD and only 7% reported The limited representation of CKD patients in cardiovascular outcome stud such as COURAGE and SYNTAX, which help shape current revascul COURAGE and SYNTAX, approximately 14% and 16% of patients w respectively(7,10). Moreover, multiple studies have shown an association rates of procedural complications and adverse outcomes following revas the balance of risk versus benefit of revascularization with either percuta (PCI) or coronary artery bypass graft surgery (CABG) and compared to opt remains to be defined (1,2,6,11,12).

METHODS:

We analyzed data from patients who underwent PCI and were prospectiv

Cardiac Outcomes Registry (VCOR) between January 2014 and December

clinical registry established to improve the quality of care in cardiov

Australia (19). The registry is coordinated by Monash University. The

related to PCI procedures gathered from 30 public and private hospital

patients undergoing PCI are given information on the registry and an opt-ou

A steering committee with representation from contributing centres overs

a peer-review committee audits and monitors data collection and outc

participating site has received approval from their local human research

analyzed data from all patients in the VCOR PCI module who had a pre-pro

Estimated creatinine clearance (CrCl) was calculated using the Cock

(mL/min)=([140-age]x weight [Kg])/(serum creatinine [mg/dL] x72) (x0.8

blood samples(20). Patients were stratified into tertiles according to ba

filtration (eGFR); eGFR $\geq$60mL/min, eGFR30-59 mL/min and eGFR<

replacement therapy (RRT)). The primary outcome was long-term all-ca

data linkage with the Australian National Death Index (NDI). Secondar

major adverse cardiovascular or cerebrovascular event (MACCE; compo

infarction, stent thrombosis, unplanned revascularization or stroke). Pat haemorrhagic), rehospitalization (including cardiac, PCI, CABG, and plan vessel revascularization (TVR), target lesion revascularization (TLR), medications at 30-days. Major adverse cardiac events (MACE) were mortality, myocardial infarction, stent thrombosis, and unplanned revascu MACE variables with the addition of stroke.

Statistical analysis:

Continuous variables are presented as medians and interquartile ranges or (as appropriate). Categorical variables are presented as frequencies and p tailed and assessed at the 5% significance level. Comparisons of continuo using paired or unpaired *t* tests for normally distributed data or the Wilco transformation for skewed data, with additional Bonferroni's correction were assessed using the Chi square test, Fisher Exact or McNemar test for Meier methods was used for time-to-event outcome comparisons. Surviv time of index revascularization to death or censored at the closing date of Cox proportional hazard modelling, which included univariate variables w the model, was performed to assess for independent predictors of long-term performed using StataCorp. 2013. Stata Statistical Software: Release StataCorp LP.

replacement therapy) were categorised into 3 cohorts according to tertiles
mL/min, eGFR30-59 mL/min and eGFR<30 mL/min, respectively.
differences were observed between eGFR groups. Those with eGFR ≥60 w
a mean age of 63 years +/- 11, compared to those with eGFR 30-59 (77 ye
years+/-8), p<0.001. Among all patients, 76% were male, however, the pro
in those with worsening renal impairment (eGFR≥60:20% vs eGFR30-5
p<0.001. Renal impairment was also associated with increased rate
conditions such as diabetes mellitus (eGFR≥60:21% vs eGFR30-59: 26%
CABG (eGFR≥60:7% vs eGFR30-59: 13% vs eGFR<30:16%) and
(eGFR≥60:3% vs eGFR30-59: 7% vs eGFR<30:12%), p<0.001.

Left ventricular (LV) systolic dysfunction was more common in the red
eGFR <30 patients were observed to have severe LV dysfunction (ejectio
with 9% and 4% in the eGFR 30-59 and ≥60 groups, respectively (p<0
presentation was more frequently observed in those with CKD, 7.0% of p
in cardiogenic shock prior or at the time of PCI, compared with 4% and
patients, respectively p<0.001. Acute coronary syndrome (STEMI and N
more frequently the indication for PCI in the eGFR <30 (19 and 38%) grou
59 (15 and 31%) and eGFR ≥60 (16 and 32%), p<0.001 (Table 2). Conve
30-59 (28%) had a greater proportion of patients undergoing PCI for chro

CKD severity was also associated with increased coronary lesion comp ACC/AHA coronary lesion classification system. Additionally, a greater were performed on the left main coronary artery (6%) and bypass grafts (5 p<0.001. Of note, those in the eGFR<30 (92%) and eGFR 30-59 (93% successful treated lesion(s) compared to eGFR ≥60 (94%), p<0.001.

In hospital and 30-day outcomes

In hospital outcomes are shown in Table 3. The median in-hospital le increasing severity of CKD; eGFR <30 (5 days; IQR 2-9); and eGFR 30-59 ≥60 (2 days; IQR 1-4), p<0.001. BARC type 3a-5 (excluding BARC 4) bl patients with eGFR<30, 1.7% in eGFR 30-59 and 0.7% of eGFR≥60, p<0 kidney injury and need for post procedural dialysis was higher in those wit and eGFR 30-59 (7.2% and 1.1%), compared with eGFR ≥60 (2.3% and in-hospital mortality (eGFR<30; 9.8% and eGFR 30-59; 3.7% vs. eGF (eGFR <30; 10.9% and eGFR 30-59; 5.0% vs eGFR≥60; 2.2%) were more dysfunction groups, all p<0.001.

At 30-day follow-up (Table 3), there was no difference in rates of stent th and without renal impairment. There was, however, significantly inc infarction, clinically significant bleeding and rehospitalization in the CKD

term mortality for the study population was 7.8% with a step-wise increa
function (eGFR <30 requiring RRT 40% vs eGFR <30 no-RRT 38%, eG
14% vs eGFR≥ 60 4.5%), p<0.001. After multi-variable analysis, wors
independently associated with increased risk of mortality; adjusted HR for
7.5 [CI 6.3-9], 3.3 [CI 2.8-3.9] for eGFR <30 no-RRT, 2.1 [CI 1.9-2.4] f
1.4-1.8] for eGFR 45-59, when compared to eGFR>60, all p<0.001 (Figur

DISCUSSION:

In this large, contemporary all-comers PCI population, increasing severity
higher rates of adverse clinical events following PCI over both short and lo
clinical outcome metrics such as length of hospitalization, major bleeding
day mortality and MACCE were increased among CKD patients. There w
long-term NDI-linked mortality, commensurate with worsening CKD sev
CKD following multivariable analysis remained a significant independ
mortality when adjusted for increased burden of comorbid conditions, age
at the time of presentation for a revascularization procedure. These find
prognostic impact of impaired renal function on all measures of clinical o
comers population.

Beyond being just a biomarker for a higher risk cohort of patients

patients with an eGFR of <60. Furthermore, when assessing the optimal n multivessel CAD with CABG versus PCI - a common clinical scenar SYNTAX and FREEDOM only included 16% and 17% of patients with C with the widespread use of drug eluting stents (DES), the BIONYX (T Durable Polymer-Coated Versus Ultrathin Cobalt-Chromium Strut, Bio Drug Eluting Stents in Allcomers With Coronary Artery Disease) trial on with CKD (21). In this context, the current decision-making process re CKD patients is predicated upon insufficient and, to an extent deficient data for this patient population. Indeed, patients with CKD appear to characterised by multiple high-risk co-morbidities which we have demo therefore, require dedicated data to guide revascularization decisions, whic

Patients undergoing PCI with CKD, compared to those with preserved re to have several pre-procedural features that increase the risk of adverse cl analysis of the EVENT (Evaluation of Drug Eluting Stents and Ischaemic year outcomes post PCI with DES, and reported increased rates of tra factors, LV dysfunction, prior coronary intervention or CABG, and increas patients with an eGFR of <75 (5), similar to the findings from our study. T and procedural characteristics likely underpin the reason why patients with cohort when being treated with PCI. In fact, in a large provincial database greater risk of hemodynamic instability and lower probability of procedura

poorer short and long-term outcomes (2,5,25).

The pathophysiological mechanisms responsible for the CKD ph

multifactorial. Patients with CKD are known to have a chronic inflamm

increased oxidative stress, derangement in calcium-phosphate haemost

calcification.(26,27), In addition, increased rates of diabetes, and hype

observed in the CKD population are likely to compound vascular inflamn

sequelae (28–30).

In our study population, 50% of those receiving PCI with CKD (eGFR <60

of ACS, underscoring the sizeable proportion of CKD patients with ACS w

treatment. Revascularization in the context of ACS has a robust body

prognostic benefits in those with preserved renal function(31,32). In the a

trials, CKD patients presenting with STEMI continue to undergo emerge

same manner as those with normal kidney function (33,34). The unadjust

STEMI patients in our cohort was 34% in the eGFR <30 group, compared

function cohort. This finding underscores the high risk of adverse outcom

impairment presenting with STEMI, which is consistent with those

registry(15). For patients with NSTEMI and CKD, there are no randomiz

therapy alone versus PCI. A meta-analysis of several landmark trials poo

Among patients with eGFR <30 and eGFR 30-59, approximately 1 in 5 pa indication of stable CAD. In the setting of increased coronary lesion c dysfunction and other high-risk features being more prevalent in those with regarding the risk-benefit of proceeding with PCI needs to be undertaken be obtained from PCI, the recent ISCHAEMIA-CKD (International St Effectiveness With Medical and Invasive Approaches – Chronic Kid demonstrate prognostic benefit from PCI compared with OMT in pat Furthermore, ISCHAEMI-CKD demonstrated increased need for RRT invasive strategy. Similarly, in our cohort we observed that increased sev was associated with higher rates of acute kidney injury and need for pos secondary to contrast administration. In a meta-analysis by *James* and kidney injury was strongly associated with increased risk of mortality progression to end-stage renal disease, prolonged hospitalisation(34). Thes the need for careful patient selection in those with CKD undergoing PCI fo patients will derive significant symptom relief and the risk of procedural c

Increasing severity of CKD was found to be an independent predictor of lo PCI. An eGFR <30, in particular those needing RRT, was the most signific long-term all-cause mortality. Interestingly, severe CKD conferred a greate than severe left ventricular dysfunction, cardiogenic shock, pre-proced management of CAD, for example PCI vs CABG vs OMT, in patients wit to include these patients in future randomized controlled trials.

LIMITATIONS

Our study findings need to be interpreted with acknowledgment of several is heterogeneity between the eGFR groups as seen through a range of confounders with respect to the primary and secondary end-points of attempted to account for these measured confounders through a multivari unmeasured variables that could also impact upon the outcomes of the s long-term mortality data are derived from the National Death Index, outcomes such as the mode of death, repeat hospitalizations, which wo patients in the VCOR registry all underwent PCI, and we do not have data o angiography, or were managed medically or underwent surgical revascula

CONCLUSION:

In this large, all-comers, PCI registry, the severity of CKD was associated risk of short-term adverse outcomes and long-term all-cause mortality,

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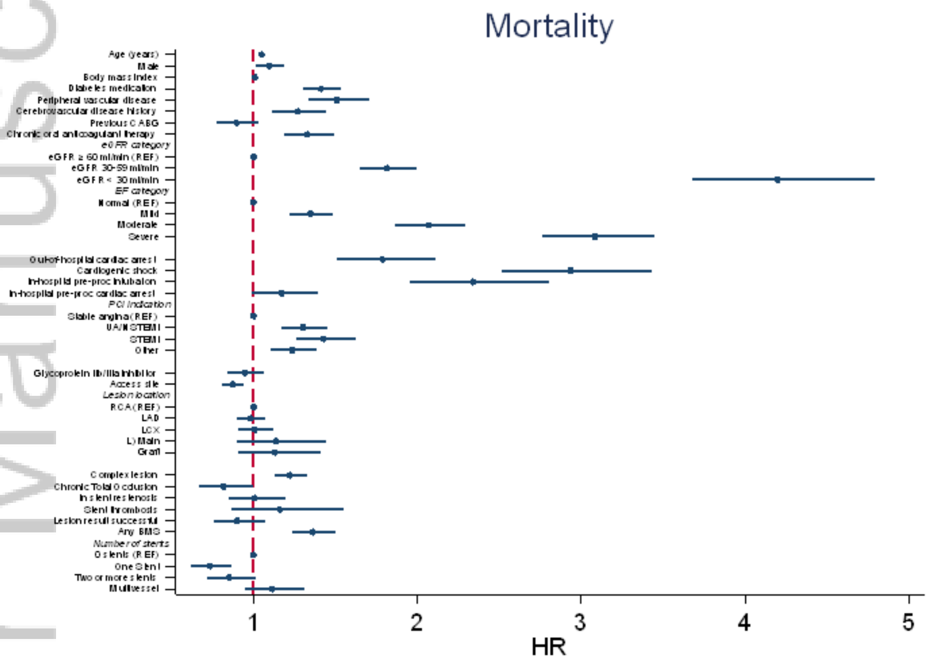
Figures and table headers:

Table 1: Baseline pre-procedural characteristics



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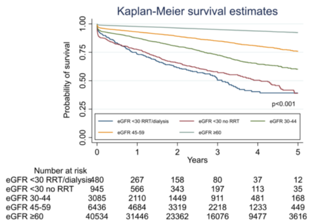

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Table 1: Baseline pre-procedural characteristics:

		eGFR<30 (n=1425)	eGFR 30-59 (n=9521)
Age, mean +/- SD, years		76.6 +/- 12.6	77.6 +/- 8.3
Male		816 (57%)	5890 (62%)
Body mass index, mean +/- SD (Kg/m^2)		25.8 +/- 5.2	26.2 +/- 4.5
Diabetes medication		562 (39%)	2500 (26%)
Diabetes medication type	Oral	227 (40%)	1626 (65.0%
	Insulin	335 (60%)	874 (35.0%)
Peripheral vascular disease		174 (12%)	636 (6.7%)
Cerebrovascular disease history		137 (9.6%)	612 (6.4%)
Previous CABG		223 (16%)	1219 (13%)
Chronic oral anticoagulant therapy		143 (10.0%)	997 (10.5%)
Creatinine, median (IQR)		218.0 (150.0, 449)	107.0 (88.0,
Renal Replacement Therapy		467 (33%)	
Ejection Fraction	Normal	525 (47%)	4936 (61%)
	Mild	241 (21%)	1446 (18%)
	Moderate	189 (17%)	997 (12.4%)
	Severe	175 (16%)	682 (8.5%)
Out-of-hospital cardiac arrest		27 (1.9%)	230 (2.4%)
Cardiogenic shock		100 (7.0%)	381 (4.0%)
In-hospital pre-procedure intubation		50 (3.5%)	271 (2.8%)
In-hospital pre-procedure cardiac arrest		31 (2.2%)	193 (2.0%)

Table 2: Procedural characteristics

		eGFR<30 (n=1425)
PCI indication	STEMI	265 (19%)
	PCI post cardiac arrest or cardiogenic shock (non MI)	11 (0.8%)
	NSTEACS	536 (38%)
	PCI for stable angina	259 (18%)
	Staged PCI	109 (7.6%)
	Other PCI	233(16%)
Door to balloon time, median (IQR)		89(56, 154)
Symptom to balloon time, median (IQR)		266 (167, 503)
Access site	Radial	345 (24%)
	Femoral	1077 (76%)
	Brachial	3 (0.2%)
Lesion location	RCA	439 (31%)
	LAD	506 (36%)
	LCX	331 (23%)
	Left Main	78 (5.5%)
	Graft	71 (5.0%)
ACC/AHA lesion classification		
	A	79 (5.5%)
	B1	383 (27%)
	B2	530 (37%)
	C	433 (30%)
Multiple lesions treated		165 (12%)
Chronic Total Occlusion		51 (3.6%)
Lesion(s) successfully treated		1308 (92%)

Table 3: In hospital and 30-day outcomes

		eGFR<30 (n=1425)	eGFR 30-5 (n=9521)
In-hospital outcomes			
Length of Stay, median (IQR)		5 (2-9)	3 (1-5)
New renal impairment		203 (17%)	506 (7.2%
Post-procedure dialysis		54 (4.6%)	76 (1.1%)
In-hospital shock		101 (7.1%)	306 (3.2%
In-hospital MI		19 (1.3%)	78 (0.8%)
TVR (PCI)		10 (0.7%)	60 (0.6%)
TLR		6 (0.4%)	49 (0.5%)
In-hospital CABG		3 (0.2%)	69 (0.7%)
Planned CABG		2 (0.1%)	34 (0.4%)
TVR requiring CABG		3 (0.2%)	46 (0.5%)
Stent thrombosis (definite/probable)		7 (0.5%)	33 (0.3%)
Major bleeding		36 (2.5%)	154 (1.6%
Stroke	No stroke	1418 (99.5%)	9482 (99.6
	Haemorrhagic	2 (0.1%)	10 (0.1%)
	Ischaemic	5 (0.4%)	29 (0.3%)
Mortality		140 (9.8%)	356 (3.7%
MACE		150 (11%)	453 (4.8%
MACCE		155 (11%)	477 (5.0%
30-Day Outcomes			
Myocardial infarction		26 (2.1%)	127 (1.5%
Stent thrombosis (definite/probable)		7 (0.6%)	46 (0.5%)
Major bleeding		45 (3.2%)	215 (2.3%
Stroke	No stroke	1208 (99.8%)	8709 (99.8
	Haemorrhagic	1 (0.1%)	8 (0.1%)
	Ischaemic	2 (0.2%)	10 (0.1%)
Rehospitalisation		259 (21.%)	1372 (16%

Table 4: 30-day outcomes stratified by PCI indication

		eGFR<30 (n=1425)	eGFR 30-59 (n=9521)
STEMI	Mortality	95 (34%)	293(18%)
STEMI	MACE	99 (36%)	339(21%)
NSTEMI/Unstable Angina	Mortality	44 (8.2%)	81(2.7%)
NSTEMI/Unstable Angina	MACE	54(10%)	144(4.9%)
Stable Angina	Mortality	16 (4.5%)	57(2.5%)
Stable Angina	MACE	20(5.7%)	85 (3.8%)