

# Retrospective comparative study of the short and long term outcomes of primary coronary intervention(PCI)vs coronary artery bypass graft (CABG) in chronic kidney disease (CKD) population. The outcomes include deaths, recurrence of acute coronary syndrome (ACS), bleeding complication, heart failure and hemodialysis dependence after the procedure

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## Research article

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# Abstract

## Background

Occurrence of cardiovascular disease and deaths is more in patients with chronic kidney disease. For patients with Chronic kidney disease (CKD) and multivessel coronary artery disease (CAD), the optimal revascularization study is still debatable. This is a single center retrospective study to compare the short- and long-term outcomes of PCI vs CABG in CKD patients who presented with in Sri Lanka. The study was aimed to compare the outcomes of PCI vs CABG in cohort of CKD patients in Sri Lanka who presented with acute coronary syndrome.

## Methods

A retrospective comparative study was conducted at Sri Jayawardenapura General Hospital on patients with CKD who underwent CABG and PCI since 2013 to 2017. Patients with CKD who underwent PCI, the outcomes were matched to patients who underwent CABG for multivessel disease by using univariate and multivariate statistical analysis methods. The outcomes include deaths, recurrence of acute coronary syndrome, LV dysfunction, bleeding complications and stroke. Data were obtained from past medical records, clinic records and telephone interviews.

## Results

There were 423 patients met inclusion criteria with mean age  $59.94 \pm 8.381$  years. There were 81.3% (n = 344) of males. The prevalence of Diabetes, hypertension, dyslipidemia in the study sample was 89.2% (n = 363), 83.3% (n = 339), and 34.9% (n = 142) respectively. The prevalence of CKD stage I and II, III, IV and V was 38% (n = 165), 36.9% (n = 156), 12.5% (n = 54), 11.3% (n = 48) respectively. The recurrence of ACS in PCI group was 14.3% (n = 34), 23.6% (n = 56), 12.7% (n = 30) compared to CABG group 7.5% (n = 14), 7% (n = 13), 0% in 1 month, 1 year and 3 years' time ( $X^2 = 4.817$ ,  $p < 0.05$ ,  $X^2 = 21.136$ ,  $P < 0.01$ ,  $P < 0.05$ ). There was a statistically significant reduction in recurrences of ACS in CABG group compared to PCI group in CKD population. The incidence of LV dysfunction in the PCI group was 24% (n = 18), 50.7% (n = 38), 29.3% (n = 22) compared to CABG group 8% (n = 12), 20% (n = 3), 0% in 1 month, 1 year and 3 years ( $p < 0.05$  using fishers exact test). There was a significant reduced occurrence of LV dysfunction in CABG group compared to PCI group in 1 year and 3 years' time.

## Conclusion

In conclusion, most of the CKD population with acute coronary syndrome were males with younger age group. Also, most of them had associated risk factors include hypertension, diabetes mellitus and dyslipidemia. The CKD population had presented with acute coronary syndrome at relative younger age might be due to associated risk factors. There was no difference in mortality rate between CABG vs PCI in CKD population. However, there was a significant reduction in recurrence of acute coronary syndrome, LV

dysfunction, bleeding complications and stroke in CABG group than PCI group in CKD population. There was no significant association of end up in dialysis following PCI or CABG.

## Background

*The chronic kidney disease (CKD) patients experience the mortality and morbidity due to Cardiovascular disease. Atherosclerosis, vascular calcification, which resulting in coronary artery disease are more common in patients with CKD. Apart from the medical management it is a difficult and very important decision to take that what type of coronary artery revascularization to be needed and when that to be done in all patients with coronary artery disease. Still, there is a treatment risk contradictory, in that these high-risk patients have lower rates of medical therapy, referral for cardiac stress testing and cardiac revascularization when compared to lower risk patients. European Society Cardiology (ESC) guidelines recommended that acute coronary syndrome (ACS) with multivessel disease opted for either PCI or CABG. Clinical status of the patient, the coronary artery disease (CAD) severity and distribution and characteristics of the the lesion should be conceded when deciding the revascularization for a patient.*

*Even though CABG and PCI are suitable for most patient, the decision must be taken by the care team and patient to achieve the better patient centered care. The complications such as higher rates of repeat revascularization and possible recurrent Myocardial infarction are associated with PCI. At the same time CABG is associated with higher rate of stroke and periprocedural death. But it is debatable when applying same rules in CKD and non-CKD patients with CAD. Interaction between uremic cardiomyopathy and arteriosclerosis causes a complex output in CKD which change the biology of heart disease.*

## Methods

*The study was a single center retrospective comparative study conducted in Sri Jayawardenapura General Hospital. Ethical approval for the study was obtained from Ethical review Committee, Sri Jayawardenapura General Hospital.*

*The main objectives in our study are to describe the sociodemographic distribution of the population with CKD and acute coronary syndrome, to compare the baseline characteristics with outcomes include recurrence of ACS and LV (left ventricular dysfunction) and to compare the short- and long-term outcomes of PCI vs CABG in CKD population.*

Patients with CKD who underwent PCI, the outcomes were matched to patients who underwent isolated CABG for multivessel disease by using univariate and multivariate statistical analysis methods. The definition of CKD was estimated GFR < 90 ml/min/1.73 m<sup>2</sup> and it was divided into 5 stages (I-V). In our study CKD again classified into mild (stage 1 and 2), moderate (stage 3 and 4), severe (stage 5). The categorical variables included age, gender, diabetes mellitus, hypertension, dyslipidemia, and family history of ischemic heart disease. The outcomes were observed in 1 month, 1 year and 3 years' time. The outcomes include heart failure, deaths, recurrence of ACS and dependence of hemodialysis and bleeding.

### ***Inclusion Criteria***

1. Patients with CKD defined as those with an estimated GFR less than 90ml/mt(calculated using the MDRD study equation)
2. Patients with multivessel disease defined as severe stenosis (>70%) in at least 2 major coronary arteries
3. *Patients underwent PCI with drug eluding or bare metal stents and patients who underwent isolated CABG*

### **Exclusion criteria**

1. Patients who underwent prior cardiac surgery or prior PCI
2. Patients with primary valvular heart disease.
3. *Patients who underwent renal transplantation.*
4. *Patients who were lost to follow up regularly in the clinic visits.*
5. *Patients who had not given the consent for telephone interview*
6. *Patients with significant life limiting co-morbidities like advanced metastatic cancer.*
7. *Patients who underwent balloon angioplasty*
8. *Patients who received isolated medical treatment*

### **Sample size calculation-**

*The sample size will be 423 according to following formula*

$$N = \frac{Z^2 (p \times q)}{d^2}$$

*N= Sample size*

*P= Rough estimate for proportion of occurrence of event being measured 50%.*

*Z= Significant level at 95% confidence limit 1.96*

$$q = (1-p)$$

*d = The degree of accuracy (precision) desired for margin of error set at 0.05 (5%)*

$$N = \frac{1.96^2 \times 0.5 [1 - (0.5)]}{0.05^2} = 384$$

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0.05<sup>2</sup>

Considering nonresponse rate of 10%

Total sample size of the study is **423**.

The sample size of this study was based on the number of CKD patients admitted to Sri Jayawardenapura General Hospital who underwent CABG and PCI since 2013 January 1<sup>st</sup> to 2017 December 31<sup>st</sup>. Data of all patients (included in inclusion criteria) with CKD who underwent CABG and PCI at Sri Jayawardenapura General Hospital were collected by past medical records, clinic records and telephone interviews.

### **Ethical clearance**

Informed written concerned was taken from all participants. Ethical clearance was obtained from ethical review committee, Sri Jayewardenepura General Hospital.

### **Data collection**

Data was collected from all the patients past medical and clinic records and telephone interviews.

### **Data analysis**

Categorical variables include gender, smoking, history of diabetes mellitus, history of hypertension, history of dyslipidemia and family hx of ischemic heart disease. Categorical variables were described as frequencies and percentages.

The interactions in between categorical variables were estimated using the chi-square test and fisher's exact test. Those baseline characteristics were compared with the outcomes by using chi-square test and fisher's exact test.

The outcomes including deaths, recurrence of ACS, bleeding, left ventricular dysfunction and end up in hemodialysis were compared with the PCI vs CABG in CKD population using chi-square test and fishers exact test. The P value < 0.05 was accepted as statistically significant. Data was analyzed using SPSS (version 22).

## **Results**

There were 423 patients met inclusion criteria with mean age  $59.94 \pm 8.381$  years. There were 81.3% (n=344) of males. The prevalence of Diabetes, hypertension, dyslipidemia in the study sample was 89.2% (n=363), 83.3% (n=339), and 34.9% (n=142) respectively. The prevalence of CKD stages I and II, III, IV and V was 38% (n=165), 36.9% (n=156), 12.5% (n=54), 11.3% (n=48) respectively (Table 1). The recurrence of ACS in PCI group was 14.3% (n=34), 23.6% (n=56), 12.7% (n=30) compared to CABG group 7.5% (n=14), 7%

(n=13),0% in 1 month, 1 year and 3 years' time. ( $X^2=4.817,p<0.05$ ,  $X^2=21.136,P<0.01,P<0.05$ ) There was a statistically significant reduction in recurrences of ACS in CABG group compared to PCI group in CKD population. The incidence of LV dysfunction in the PCI group was 24%(n=18)50.7%(n=38),29.3%(n=22) compared to CABG group 80%(n=12),20%(n=3),0% in 1 month,1 year and 3 years. ( $p<0.05$  using fishers exact test) There was a significant reduced occurrence of LV dysfunction in CABG group compared to PCI group in 1 year and 3 years' time.

**Table 1: Demographics and baseline characteristics. (n=423)**

Characteristics.	n	%
<b>Age (years)</b>		
≤50 years	42	9.9
51 - 55	60	14.2
56 - 60	114	27.0
61 - 65	111	26.2
66 - 70	66	15.6
> 70	30	8.1
Mean 59.94 + or - 8.381		
<b>Gender</b>		
Male	344	81.3
Female	79	18.7
Smoking	258	61.0
Family history of ischemic heart disease	90	22.1
Diabetes	363	89.2
Hypertension	339	83.3
Dyslipidemia	142	34.9
<b>CKD Stage</b>		
Stage I	6	1.4
Stage II	159	37.6
Stage III	156	36.9
Stage IV	54	12.8
Stage V	48	11.3
Dialysis in Stage V	19	4.4

The recurrence of ACS in PCI group was 14.3%(n=34),23.6%(n=56),12.7%(n=30) compared to CABG group 7.5%(n=14),7%(n=13),0% in 1 month, 1 year and 3 years time. ( $X^2=4.817,p<0.05$ ,  $X^2=21.136,P<0.01,P<0.05$ ) There was a statistically significant reduction in recurrences of ACS in CABG group compared to PCI group in CKD population. The incidence of LV dysfunction in the PCI group was 24%(n=18)50.7%(n=38),29.3%(n=22) compared to CABG group 80%(n=12),20%(n=3),0% in 1 month,1 year and 3 years. ( $p<0.05$  using fishers exact test) There was a significant reduced occurrence of LV

*dysfunction in CABG group compared to PCI group in 1 year and 3 years' time. Survival in PCI group was 99.6%(n=236),95.8%(n=227),90.7%(n=215) compared to survival in CABG group 96.2%(n=179)95.7% (n=178)94.6%(n=176) in 1 month,1 year and 3 years' time.*

*( $\chi^2=0.002, P>0.05, \chi^2=2.274, P>0.05$ ) Even though CABG group had overall better outcomes there is no significant survival benefit in our study, might be due to lower number of stage 5 and dialysis population. The hemodialysis dependence after PCI was 6.3%(n=15) and CABG was 8.1%(n=8.1)( $\chi^2=0.476,P>0.05$ ) there is no significant difference between PCI vs CABG in hemodialysis dependence after the procedure. Bleeding complication in PCI group was 10.1%(n=24) compared to CABG group was 0( $P<0.05$  using Fishers exact test), so there were significant bleeding complications in PCI group compared to CABG group (table 4).*

Table 2-Comparison of outcomes with treatment mode

Outcome	Treatment Mode				Significant
	PCI		CABG		
	N	%	N	%	
<b>Recurrence of ACS</b>					
1 Month	34/237	14.3	14/186	7.5	$\chi^2 = 4.817, df=1, p=0.028$ ( $p < 0.05$ )
1 Year	56/237	23.6	13/186	7	$\chi^2 = 21.136, df=1, p=0.000$ ( $p < 0.01$ )
3 Years	30/237	12.7	0/186	0	Fishers exact test $p=0.000$ ( $p < 0.05$ )
<b>End up in Dialysis</b>					
	15/237	6.3	15/186	8.1	$\chi^2 = 0.476, df=1, p=0.490$ ( $p > 0.05$ )
<b>LV Dysfunction</b>					
1 Month	18/75	24.0	12/15	80.0	Fishers exact test $p=0.000$ ( $p < 0.05$ )
1 Year	38/75	50.7	3/15	20.0	Fishers exact test $p=0.045$ ( $p < 0.05$ )
+ /3 Years	22/75	29.3	0/75	0.0	Fishers exact test $p=0.018$ ( $p < 0.05$ )

<i>Bleeding complication</i>	<i>24/237</i>	<i>10.1</i>	<i>0/186</i>	<i>0.0</i>	<i>Fishers exact test p=0.000 (p&lt;0.05)</i>
<i>strokes</i>	<i>15/237</i>	<i>6.3</i>	<i>3/183</i>	<i>1.6</i>	<i>Fishers exact test p=0.000 (p&lt;0.05)</i>

Figure 7 comparison of survival between PCI vs CABG

<b>Table 3: Comparison of baseline characteristics with outcome (Recurrence of ACS)</b>					
<b>Characteristic</b>	<b>Recurrence of ACS</b>			<b>Significant</b>	
	<b>Yes</b>	<b>%</b>	<b>No</b>	<b>%</b>	
<b>CKD</b>					
Mild stage	36	25.0	129	46.2	$\chi^2=19.744,df=2,p=0.000$ ( $p<0.01$ )
Moderate Stage	84	58.3	126	45.2	
Severe Stage	24	16.7	24	8.6	
<b>Age group</b>					
<60 years	102	70.8	114	40.9	$\chi^2=34.147,df=1,p=0.000$ ( $p<0.01$ )
>60 years	42	29.7	165	59.1	
<b>Hypertension (Past history)</b>	120/139	86.3	219/268	81.7	$\chi^2=1.401,df=1,p=0.237$ ( $p>0.05$ )
<b>Dyslipidemia</b>	47/139	33.8	95/268	35.4	$\chi^2=0.108,df=1,p=0.743$ ( $p>0.05$ )
<b>Diabetes</b>	126/139	90.6	237/268	88.4	$\chi^2=0.466,df=1,p=0.495$ ( $p>0.05$ )

<b>Table 4: Comparison of baseline characteristics with outcome (LV Dysfunction)</b>					
<b>Characteristic</b>	<b>LV Dysfunction</b>			<b>Significant</b>	
	<b>Yes</b>	<b>%</b>	<b>No</b>	<b>%</b>	
<b>CKD</b>					
<i>Mild stage</i>	18	20.0	147	44.1	
<i>Moderate Stage</i>	42	46.7	168	50.5	$\chi^2=59.492,df=2,p=0.000$ ( $p<0.01$ )
<i>Severe Stage</i>	30	33.3	18	5.4	
<b>Age group</b>					
<i>&lt;60 years</i>	60	66.7	156	46.8	$\chi^2=11.138,df=1,p=0.001$ ( $p<0.05$ )
<i>&gt;60 years</i>	30	33.3	177	53.2	
<i>past history of hypertension</i>	60/90	66.7	279/317	88.0	$\chi^2=22.952,df=1,p=0.000$ ( $p<0.01$ )
<i>Dyslipidemia</i>	24/90	26.7	118/317	37.2	$\chi^2=3.439,df=1,p=0.064$ ( $p>0.05$ )
<i>Diabetes</i>	84/90	93.3	279/317	88.0	$\chi^2=2.058,df=1,p=0.151$ ( $p>0.05$ )

<b>Table 5 Comparison of treatment mode with outcomes (Treatment Mode)</b>						
<b>Baseline Characteristics</b>	<b>Treatment Mode</b>				<b>Significant</b>	
	<b>PCI</b>		<b>CABG</b>			
	<b>N</b>	<b>%</b>	<b>N</b>	<b>%</b>		
<b>Family history of IHD</b>	60/221	27.1	30/186	16.1	$\chi^2$	=7.122, df=1, p=0.008 (p<0.05)
<b>Past history of Diabetes</b>	189/221	85.5	174/186	93.5	$\chi^2$	=6.751, df=1, p=0.009 (p<0.05)
<b>Past history of Hypertension</b>	174/221	78.7	165/186	88.7	$\chi^2$	=7.224, df=1, p=0.007 (p<0.05)
<b>Past history of Dyslipidemia</b>	59/221	26.7	83/186	44.6	$\chi^2$	=14.288, df=1, p=0.000 (p<0.01)

## Discussion

*In our study we have collected data from the CKD patients who underwent CABG and PCI since 2013 January 1st to 2017 December 31st. Data was collected from past medical records follow up was done with clinic records and telephone interviews. It was not possible to collect the data from the patients who lost to follow up. In our study population the patients with CKD and coronary artery disease where younger male group might be due to association with smoking, diabetes mellitus, dyslipidemia, and hypertension.*

*Even though the association between CAD and CKD is known, there is no evidence-based treatment methods for CAD for a patient with CKD (2, 3). Without a randomized controlled study in this population, the current practices had been an option of treatment (4).*

*In a population with multivessel CAD, CABG has lower mortality compared with PCI among CKD patients who are in mild, moderate, and severe stages but this did not show any statistically significant association. However, in first month PCI group had better survival than CABG group and reached statistically significant irrespective of CKD stage. However, when compared the overall outcomes including recurrence of acute coronary syndrome, LV dysfunction and bleeding, the CABG group had better outcome than PCI group which was statistically significant in all stages of CKD.*

*A study done based on Duke Databank in years 1995–2000 where the patients underwent CABG was compared with PCI. This study showed that CABG has better mortality than PCI in patients with moderate and severe CKD (3). CABG patients showed lower risk of deaths or recurrence of acute coronary syndrome when compared with PCI in a retrospective study, but many studies included percutaneous coronary angioplasty (3–5).*

*Studies with longer term follow up indicated considerably more benefits with CABG over PCI (5–7). Even though patients with CKD have more complex CAD, our study results in CABG had better long-term outcomes than PCI group. Most studies compared only recurrence of MI and deaths, however our study compared recurrence of acute coronary syndrome, LV dysfunction, bleeding risk and dialysis dependence after the procedure. Our study also showed significant association between baseline characteristics with outcomes which other studies didn't compare. Depend on the CKD stage, hypertension, diabetes mellitus, there is a significant association with recurrence of acute coronary syndrome and LV dysfunction, which were not compared in other studies. Our study only had 19 dialysis patients: the small sample size was a limiting factor to show any differences in outcomes among different treatment groups.*

*Studies based on larger number of patient's database showed that, CABG has higher long-term benefit than PCI in in multivessel disease in dialysis patients (7–9).*

*The number of patients with severe CKD only 102 patients, compared to the lower CKD group, which was 302 patients, which was possible explanation for a lack of significant difference in mortality comparing PCI vs CABG group and there is no significant association with CKD stage and treatment outcomes.*

*Post hoc analysis of the Arterial Revascularization Therapy Study 11 trial with small number of patients with non-HD CKD did not show a statistically significant difference in CABG (15%) and PCI (12%) in the adjusted 5-year mortality rate.*

*Our databank didn't include the indication or urgency for procedure and didn't mention the type of stenting and didn't compare with the patients who underwent medical treatment only. As we have done the study in between 2013 January 1st to 2017 December 31st, all the patients had drug eluding stents in that era. CABG showed greater longer-term survival over drug eluding stents in multivessel CAD populations in an observational study (5).*

*The important finding in our study that patients underwent CABG was associated with more hemodialysis dependence (8.3%) than PCI (6.3%) this might be due to fluid shifts and sometimes using on pump procedure and due to hypotensive episodes. Also, improvement in periprocedural renal care for patients undergoing PCI, such as administration of IV fluids and acetyl cysteine might have helped to decrease the rate of renal failure after PCI.*

*The advantages of our study were both short- and longer-term outcomes were compared. There was a significant reduction in recurrence of acute coronary syndrome and LV dysfunction in CABG group compared to PCI group. Also, in our study, multiple outcomes were compared in between the treatment*

groups. We were able to identify statistically significant association with age group (56–60) and severity of CKD with recurrence of acute coronary syndrome. We were also able to identify statistically significant association with age group (56–60), severity of CKD and hypertension with LV dysfunction.

Our study had some limitations. This was a non-randomized and used observational data from a single center. The number of patients with CKD stage 5 and dialysis only 48, which was limited number compared to CKD stage 2 and 4 population. This might be the reason that there was no significant survival benefit in CABG group than the PCI group ( $p=0.967$  in 1 year,  $p=0.132$  in 3 years  $P > 0.05$ ). The selection for the revascularization method was physician dependent and the data that affected the selection was also unavailable to us. We couldn't compare the type of the stent and type of lesion as some data was unavailable as this was a retrospective study.

Statistical power of our study was limited by the small number of patients, especially in the end stage renal disease group.

#### STUDY LIMITATIONS -

1. The analysis does not control for unmeasured confounders.
2. The follow-up outcomes based on patient registries so that it is likely that the patients where records not available could have been missed.
3. Since this was a retrospective study there were selection bias and unmeasured variables that were not captured in this model.
4. *The patients who had isolated medical treatment were not compared*

## Conclusion

In conclusion, the population of CKD stage mainly in CKD stage 11 and 111. Younger age group with CKD underwent coronary intervention than the older age group. There is a statistically significant association with moderate and severe CKD group with recurrence of ACS. There is also a statistically significant association with hypertension and moderate and severe CKD stage with LV dysfunction. Even though the CABG group had showed better longer-term survival (94.6%) compared to PCI group (90.7%) it was not statistically significant in our study. This might be due to the limited number of severe CKD category. However, there is a significant reduction in recurrence in acute coronary syndrome in CABG group compared to PCI group in 1 month, 1 year and 3 years' time ( $p < 0.05$ ). There is also a significant reduction in LV dysfunction and bleeding complication in CABG group compared to PCI group ( $p < 0.05$ ). In our study there is no significant association with dialysis dependence and the procedure. However, CABG group had ended up in dialysis more than PCI group that was not statistically significant in our study. ( $p > 0.05$ ) There are several limitations in our study as it was a single centre retrospective study, the limited number of populations in our study may be the reason that some findings in our study was not statically significant. There were not enough studies done in Asian among CKD population with CAD. Therefore,

*further multicenter longer term follows up studies are needed to investigate the optimum treatment option for CKD population with acute coronary syndrome.*

## **Abbreviations**

*CKD - Chronic kidney disease*

*CAD - multivessel coronary artery disease*

*PCI - primary coronary intervention*

*CABG - coronary artery bypass graft*

*ACS - Acute coronary syndrome*

*LV - left ventricular*

## **Declarations**

*I declare that this is an original research and there is no duplication, and I didn't publish it in any other journals.*

- **Ethics approval and consent to participate:** *Ethical clearance was obtained from Sri Jayawardenapura General Hospital Ethical Committee*
- **Consent to publish** *I'm giving the consent to publish BMC Cardiovascular Disorders journal and the full text and images can be freely available on the internet*
- **Availability of data and materials:** *The datasets used and analysed during the current study are available from the corresponding author on reasonable request*
- **Competing interests:** *There is no compete of interests*
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## Contributions

NWAAGN and HC were responsible for the conception, design of the article, data collection, follow-ups. NWAAGN, HC, AS and MS were responsible for statistical processing, data interpretation and writing of the paper. All authors read and approved the final manuscript.

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## Figures

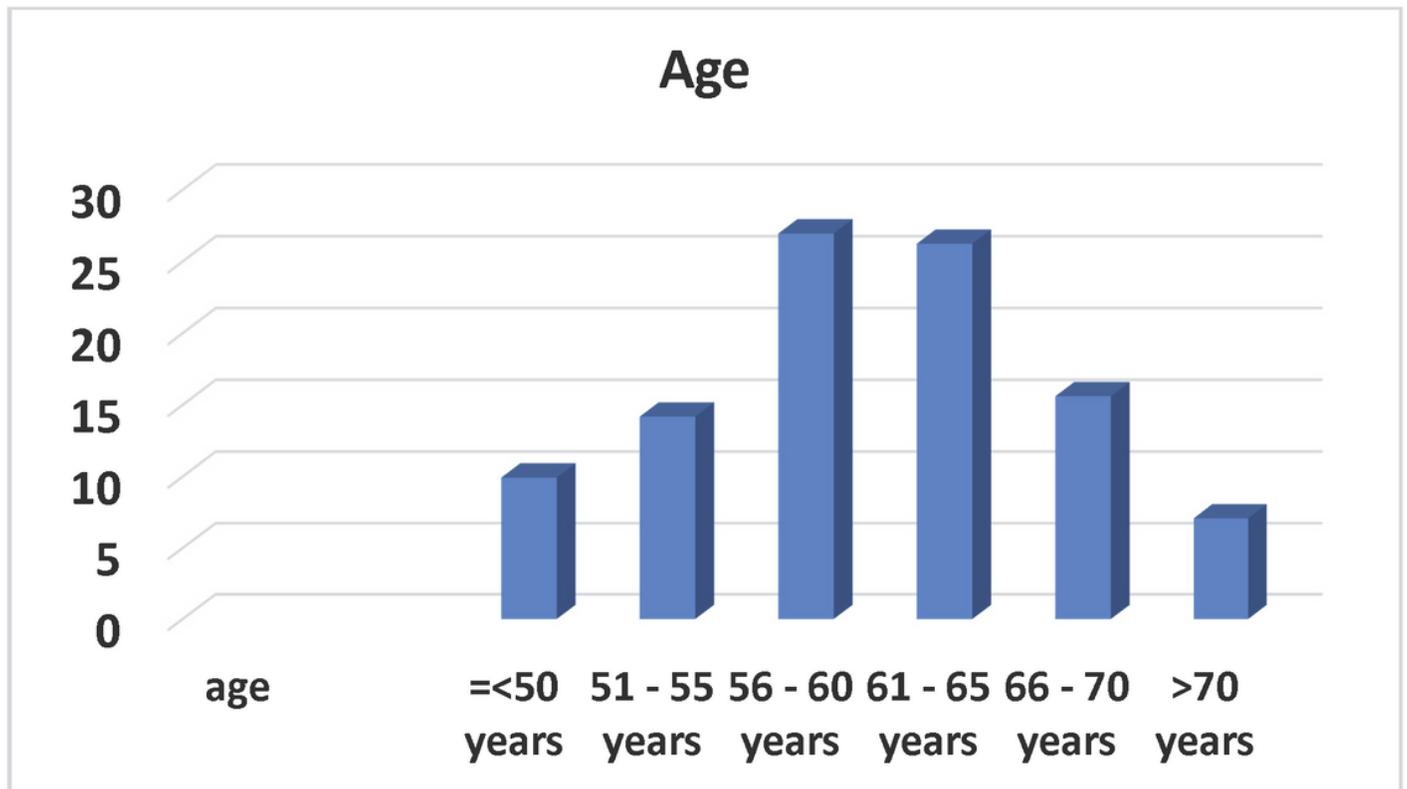
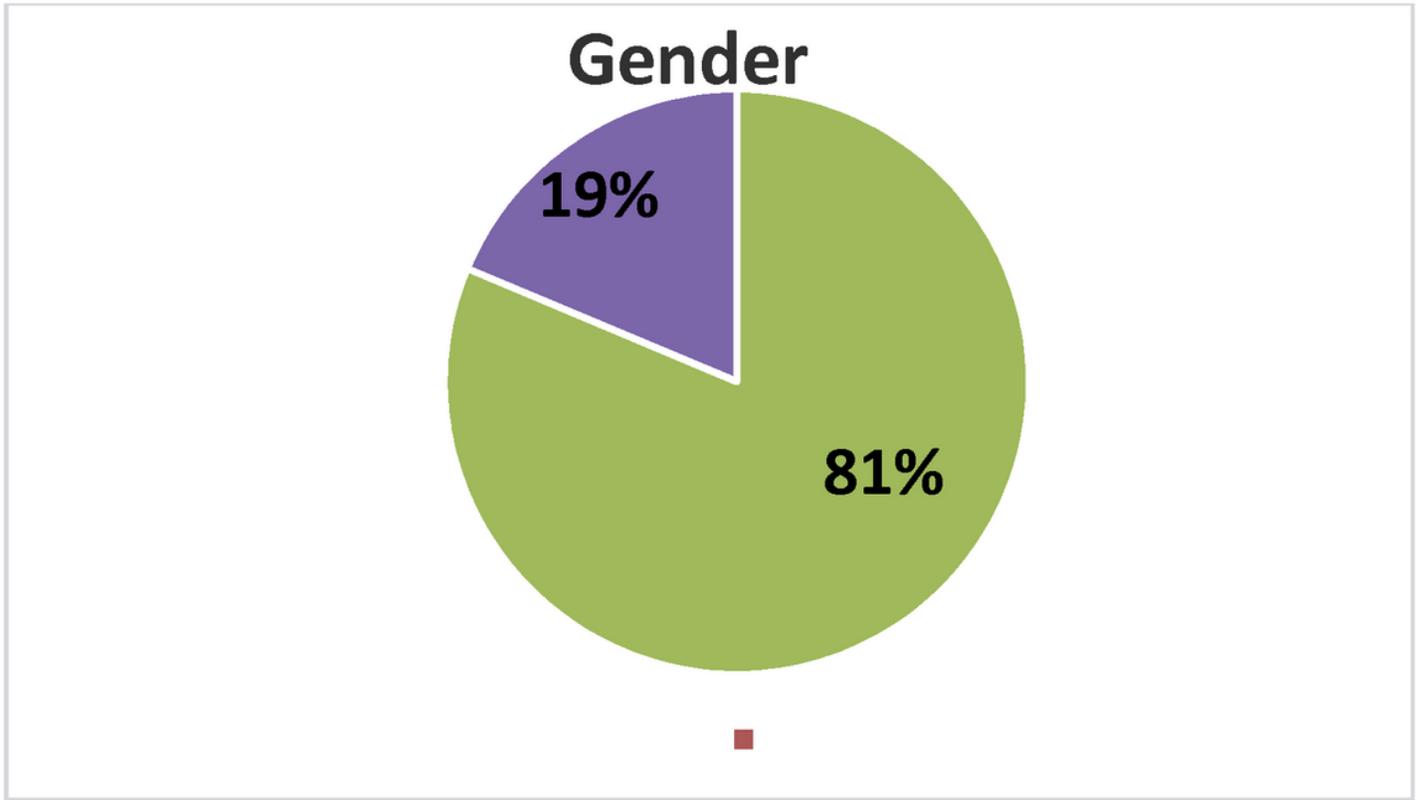


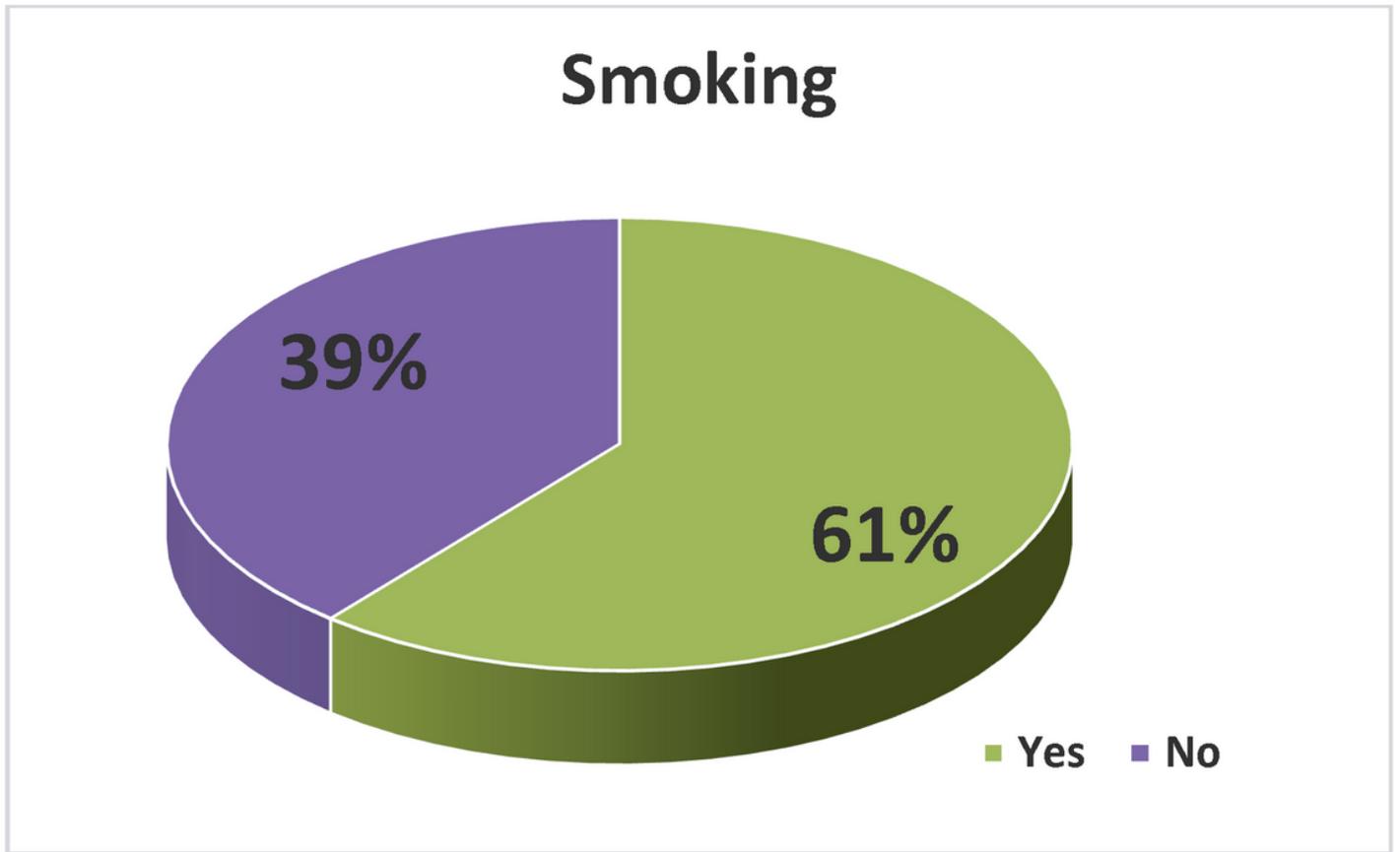
Figure 1

percentages according to age group



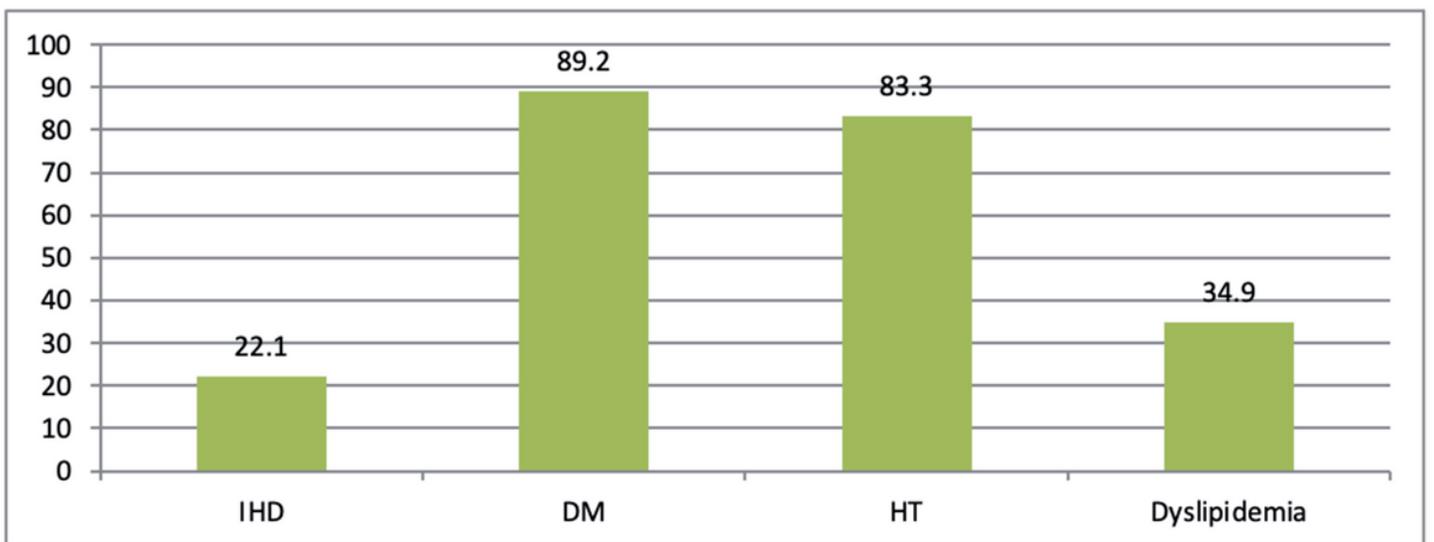
**Figure 2**

percentages according to the gender



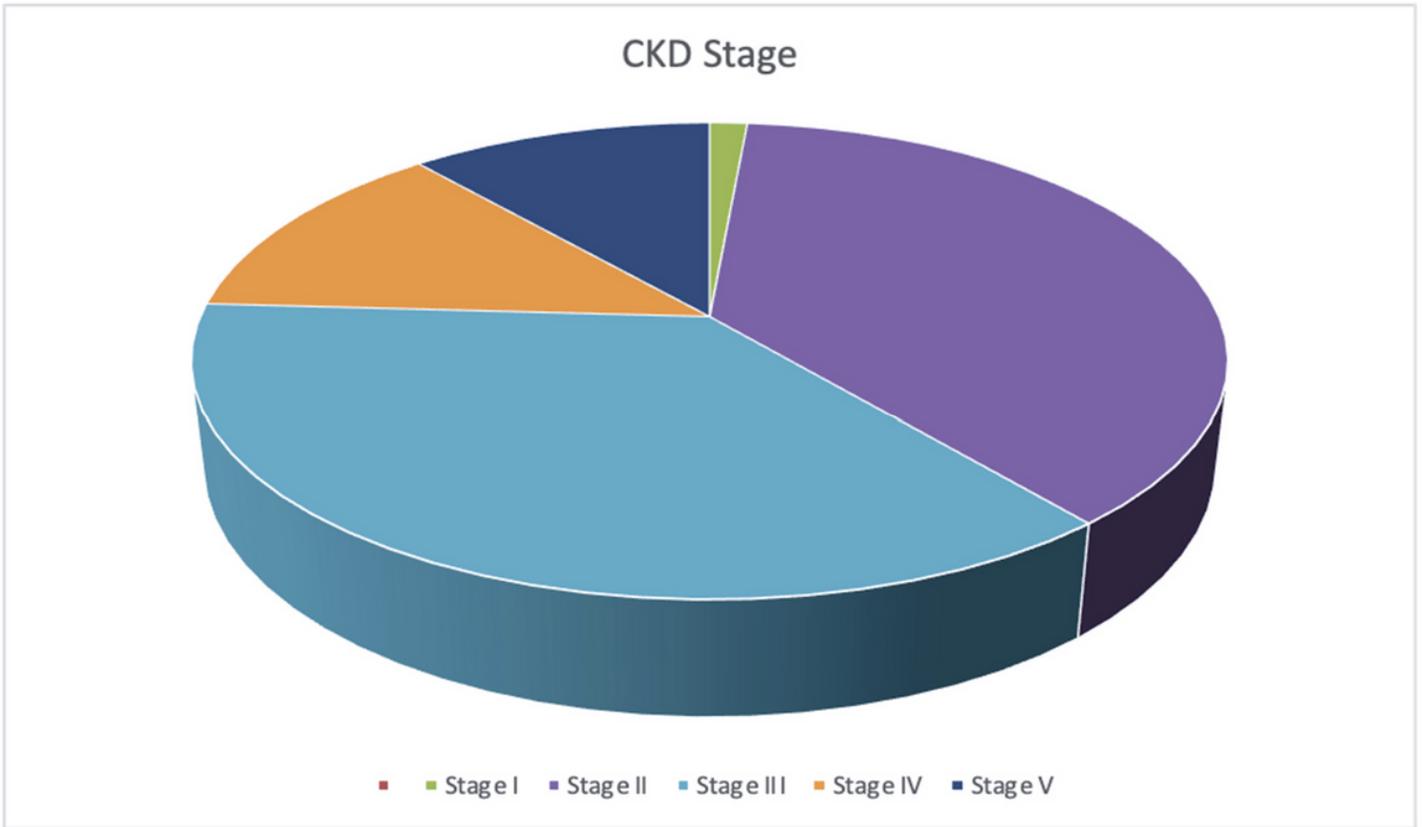
**Figure 3**

percentages of smoking



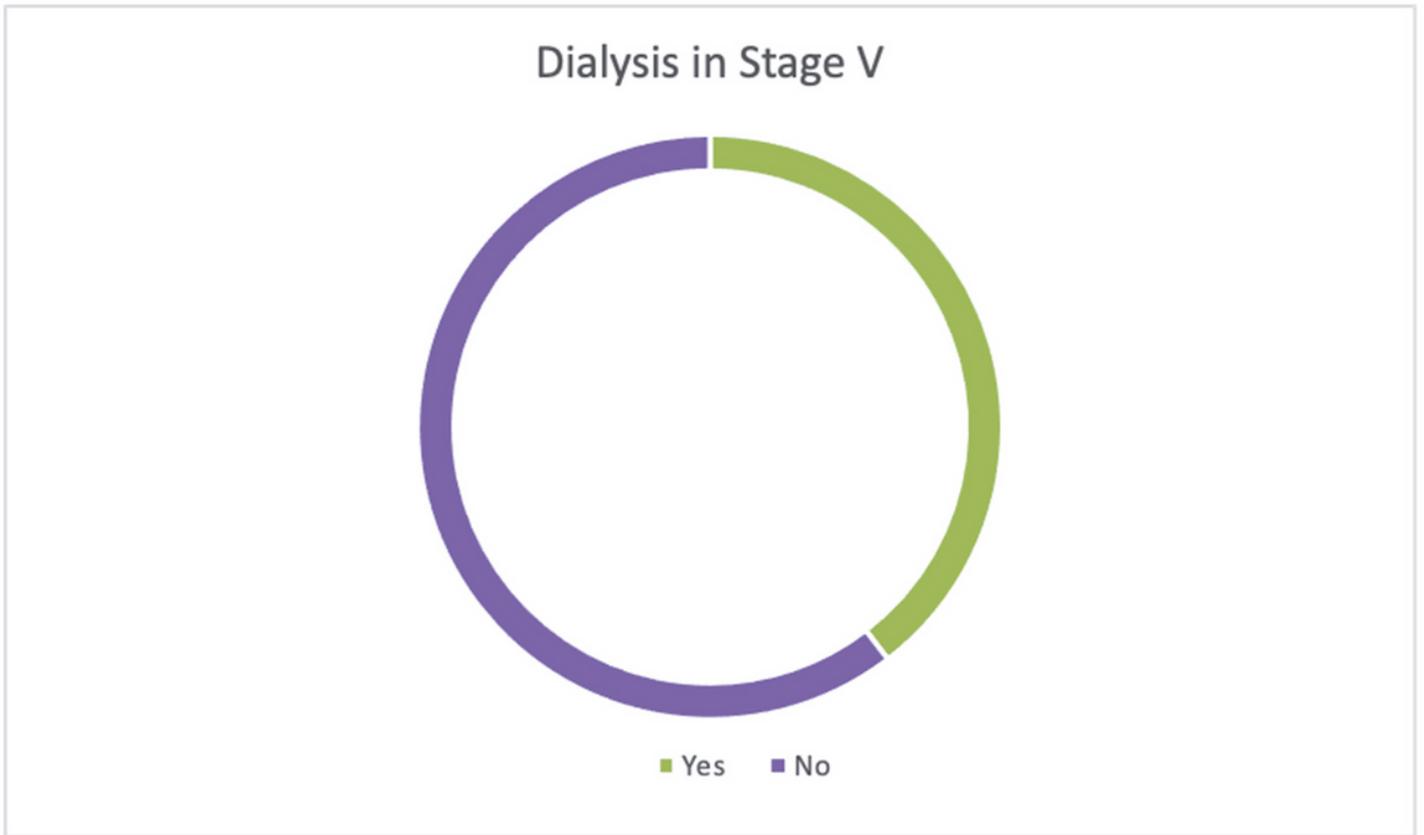
**Figure 4**

demographic characteristics of risk factors



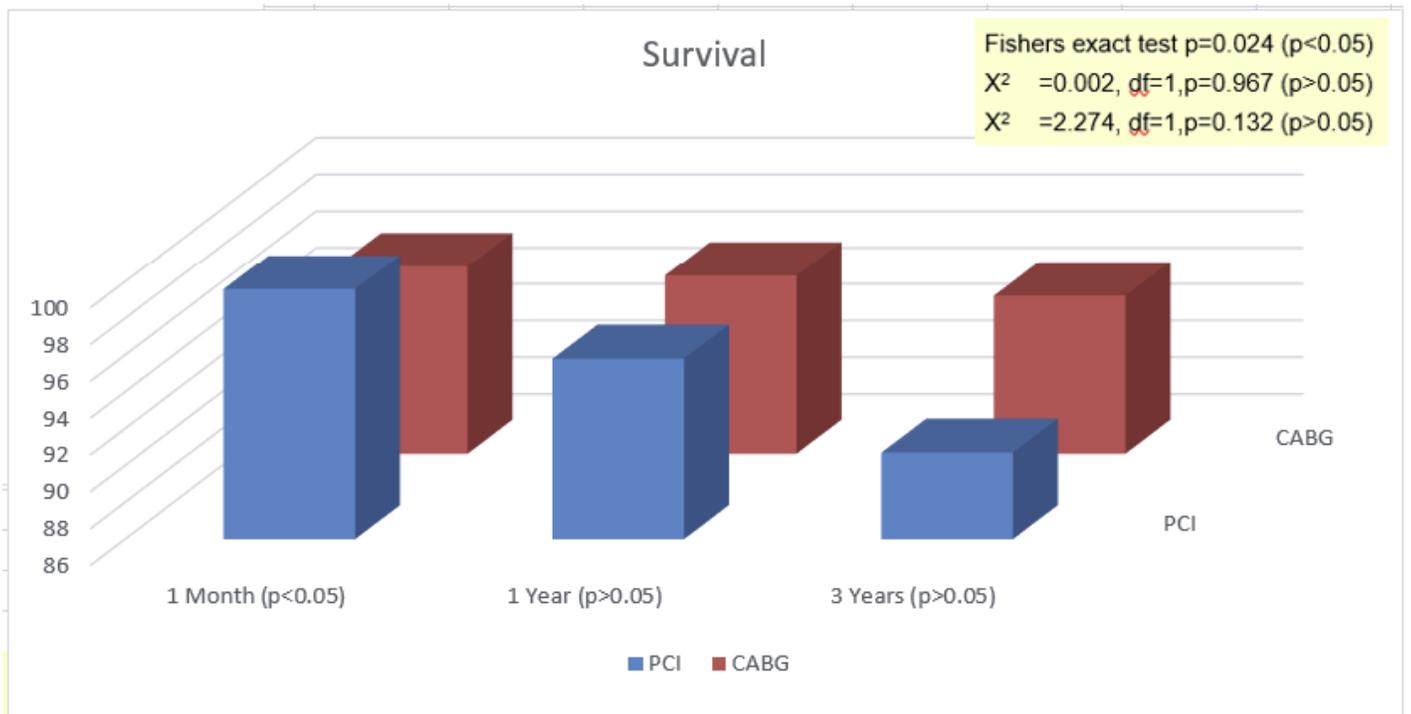
**Figure 5**

Distribution according to CKD stage



**Figure 6**

Distribution of dialysis percentage



**Figure 7**

comparison of survival between PCI vs CABG