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ORIGINAL ARTICLE

Impact of occult renal disease on the outcomes of off-pump and on-pump coronary artery bypass grafting

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Abstract

Purpose Occult renal disease (ORD) is a clinical condition in which glomerular filtration rate (GFR) is less than 60 ml/min/1.73 m^2, while serum creatinine is ≤ 1.3 mg/dl. The aim of the study was to compare the incidence of postoperative stage I acute kidney injury (AKI) according to Acute Kidney Injury Network (AKIN) classification in patients with ORD undergoing either off-pump or on-pump coronary artery bypass grafting.

Methods A single center prospective randomized study was conducted from March 2011 through January 2014. A total of 120 coronary artery disease (CAD) patients with ORD undergoing coronary artery bypass grafting (CABG) were randomized to either off-pump (group1, $n = 62$) or on-pump (group2, $n = 58$) CABG in 1:1 ratio by computer-generated random number table. The GFR and serum creatinine levels were measured preoperatively and postoperatively on day 1 and day 5. The primary outcome (postoperative AKI (stage I)) and secondary outcomes (AKI (stage III) requiring renal replacement therapy (RRT) death, myocardial infarction (MI), cerebrovascular accident, atrial fibrillation (AF), and re-exploration for bleeding) at 30 days were analyzed between the groups.

Results There is no significant difference in baseline characteristics of patients between off-pump and on-pump group. The incidence of postoperative AKI (stage I) was similar between on-pump (20.69%) and off-pump (16.13%) groups ($p = 0.51$). There was no significant difference in mortality ($p = 0.33$), postoperative MI ($p = 0.34$), cerebrovascular accident ($p = 1.00$), re-exploration ($p = 0.96$), and AF ($p = 0.50$). The number of patients of stage III AKI requiring RRT was higher in the off-pump group (3 patients, 4.8%) and none in the on-pump group ($p = 0.08$),

Conclusions This study demonstrated that on-pump CABG is associated with significantly lower GFR and significantly higher serum creatinine on postoperative day 1 which return to baseline by postoperative day 5. In patients with ORD undergoing CABG, the incidence of postoperative AKI and major adverse cardiac and cerebrovascular events were similar between off-pump or on-pump CABG patients.

Keywords ORD: Occult renal disease · GFR: Glomerular filtration rate · AKI: Acute kidney injury

Introduction

CABG is one of the most effective methods for the treatment of multivessel coronary artery disease. Preoperative renal dysfunction is recognized as a risk factor for postoperative morbidity and mortality in patients undergoing CABG [1–4]. Serum creatinine is a marker of renal function, and its serum level does not usually elevate until the GFR decreases by more than 50% [5–7]. Occult renal disease (insufficiency/impairment/dysfunction) is defined as an impaired GFR (≤ 60 ml/min/1.73m^2) with normal serum creatinine level (≤ 1.3 mg/dl) [8]. Sajja et al. reported that 30% of patients undergoing coronary artery bypass surgery had

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preoperative normal serum creatinine level, ≤1.29 mg/dL, and were in stage III of chronic kidney disease by glomerular filtration rate criteria (GFR ≤ 60 ml/min/1.73m^2), which indicates that glomerular filtration rate is a more sensitive indicator to detect renal disease early [9]. It is reported that patients with occult renal disease undergoing coronary artery bypass grafting were associated with high adverse events than in patients with normal renal function. The incidence of occult or overt renal dysfunction is on the rise in patients with coronary artery disease undergoing surgical myocardial revascularization.

Estimated creatinine clearance or GFR has been described as a more sensitive screening test in predicting renal reserve and morbidity and mortality than serum creatinine in cardiac surgery. In contrast, Cooper and colleagues analyzed the data from the Society of Thoracic Surgeon's national adult database of 4,83,914 patients undergoing CABG and suggested several measures of renal function including serum creatinine performed equally well in models predicting operative mortality. However, the information available is limited on the risk associated with occult renal dysfunction in patients undergoing CABG.

Miceli et al. [10] reported higher mortality, renal dysfunction requiring dialysis, stroke, arrhythmias, and longer hospital stay in patients with occult renal disease (ORD). Off-pump CABG technique is associated with lesser worsening of renal function in patients with non-dialysis-dependent renal insufficiency. Evidence on the reno-protection of off-pump technique in patients with ORD undergoing CABG is scarce. The aim of our study was to evaluate the effect of ORD on the incidence of AKI and early clinical outcomes in patients undergoing using either on-pump or off-pump technique.

Patients and methods

This prospective randomized study was designed to compare the effect of occult renal dysfunction on the postoperative acute kidney injury in patients who underwent elective primary coronary artery bypass grafting using either off-pump technique or on-pump technique. One hundred twenty patients met the inclusion criteria and were randomized to either off-pump ($n = 62$) or on-pump ($n = 58$) revascularization in 1:1 ratio who underwent elective primary CABG from March 2011 through January 2014. During the study period, a total of 2562 patients underwent CABG at our center. Out of which, 717 (28%) of patients were identified with occult renal dysfunction. All the eligibility criteria were strictly followed. The inclusion criteria include primary elective CABG suitable for both off-pump or on-pump coronary revascularization, age 21–70 years, GFR ≤ 60 ml/min-1/1.73 m^2, serum creatinine < 1.3 mg/dl, and left ventricular ejection fraction (LVEF) > 30%. Exclusion criteria were GFR > 60 ml/min/1.73m^2, serum creatinine > 1.3 mg/dl, emergency operation, concomitant cardiac surgical procedures, contraindication to on-pump CABG or off-pump CABG, LVEF < 30%, recent cerebrovascular accident (CVA) (< 3 months), and not willing to participate in the study.

A standard set of perioperative data was collected prospectively for all patients: age, sex, height, weight, diabetes mellitus, hypertension, peripheral vascular disease, left ventricular ejection fraction, number of significantly stenosed coronary arteries, prior myocardial infarction, angina class, serum creatinine, and GFR measured using the equation of the modification of diet in renal disease (MDRD) study. Postoperative follow-up was done during the index hospitalization, reassessed at discharge, at routine first follow-up visit, and at 4 weeks following surgery.

The primary outcome which was stage I AKI and secondary outcomes which were stage III AKI requiring RRT, death, MI, cerebrovascular accident, atrial fibrillation, and re-exploration for bleeding were analyzed at 30 days. This study complies with the principles of The Declaration of Helsinki and was approved by the institutional ethics committee, and informed consent was obtained from all the patients.

Study outcomes

Stage I AKI was defined according to AKIN classification as an increase in serum creatinine level to at least 1.5 times the baseline level [11]. A diagnosis of postoperative MI was based on the presence of new ST elevation in two or more contiguous leads in ECG. CVA was identified if there was an evidence of postoperative new-onset neurologic deficit. Postoperative atrial fibrillation was diagnosed by absence of P waves and irregularly irregular narrow QRS complexes on ECG after the procedure. Major adverse cardiac and cerebrovascular events (MACCEs) include death and postoperative MI cerebrovascular accident.

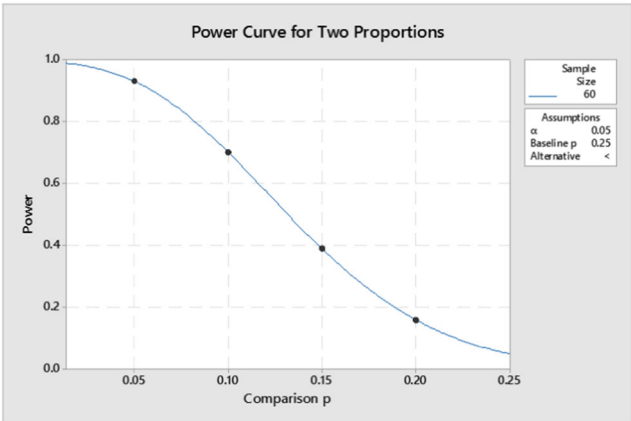
Statistical analysis

The incidence of AKI after CABG has been reported to range from 5 to 30%, depending on the criteria used to define AKI [12–15]. Hence, the sample size was calculated based on assumption that postoperative incidence of AKI either off-pump or on-pump CABG ranges from 15 to 25% with the level of significance of 5% at the power of 93%, a sample of size of 60 was determined for each group. Patients were randomly assigned to undergo either off-pump or on-pump CABG in 1:1 ratio. The randomization was done by computer-generated random number table.

The power and sample size for each group is calculated as mentioned below:

Test for two proportions
Testing comparison p = baseline p (versus <)
Calculating power for baseline $p = 0.25$, $\alpha = 0.05$

Comparison p	Sample Size	Power
0.20	60	0.160890
0.15	60	0.390612
0.10	60	0.701174
0.05	60	0.930873



All analyses were carried out on the basis of intention to treat. Statistical analysis was performed with SAS software using chi-square (χ^2) and two-sample t test to see the differences in categorical and continuous variables between on-pump and off-pump groups. All the continuous variables are expressed as a mean ±S.D. Statistical significance was accepted at probability level less than 0.05.

Surgical technique

The surgical techniques were followed as described earlier, and all operations were performed via a standard median sternotomy [9].

On-pump technique

Cardiopulmonary bypass (CPB) was instituted using ascending aortic cannulation and two-stage venous cannulation of the right atrium and conventional roller pump CPB machine. Myocardial protection was achieved by cold (4 °C) antegrade blood and potassium cardioplegia. On-pump CABG was accomplished with every effort made to minimize the impact of CPB. Distal anastomoses were performed with either 7–0 or 8–0 polypropylene continuous sutures, and proximal anastomoses were performed using 6–0 polypropylene continuous suture and with partial clamping of the ascending aorta after completion of all the distal anastomoses.

Off-pump technique

The method of exposure and stabilization to perform distal anastomoses consisted of the technique previously described [9]. The target coronary arteries were accessed by deep pericardial traction sutures or by the use of Star Fish cardiac positioner (Medtronic Inc., Minneapolis, MN). Target artery stabilization was achieved with vacuum stabilizers—Octopus 4 or Evolution (Medtronic Inc., Minneapolis, MN) or ACROBAT-i Stabilizer System (Maquet GmbH & Co, Rastatt, Germany). Intracoronary shunts were used (Medtronic Inc. Grand Rapids, MI) in all coronary arteries measuring more than 1.25 mm in diameter while constructing the distal anastomoses. Visualization of the anastomotic area was enhanced by using humidified carbon dioxide blower/mister (Medtronic Inc. Grand Rapids, MI) to disperse the blood from the site of distal anastomoses.

Results

A total of 2562 patients underwent CABG at our center during the study period from March 2011 to January 2014. Of whom, 717(28%) patients were identified with occult renal disease. A total of 120 patients met the inclusion criteria and were randomized to two groups. Group 1 (off-pump CABG, $n = 62$) and group 2 (on-pump CABG, $n = 58$). Figure 1 shows the study flow chart. The baseline characteristics between the groups were comparable (Table 1). Mean numbers of grafts per patients were similar between the groups which were 3.25 ± 0.63 and 3.14 ± 0.74 in on-pump and off-pump groups respectively ($p = 0.372$).

Two (3.45%) patients were converted from on-pump to off-pump CABG because of severe atherosclerotic changes observed in the ascending aorta, and none were converted from off-pump CABG to on-pump CABG ($p = 0.14$). Blood transfusion requirement was higher in the on-pump group compared to off-pump CABG ($p = 0.006$) (Table 2).

The incidence of postoperative AKI was similar between off-pump CABG (16.13%) and on-pump CABG (20.69%) ($p = 0.51$), but there is an upward trend towards a higher number of patients with postoperative AKI requiring renal replacement therapy in the off-pump group (4.84% vs 0.00%, $p = 0.08$). Thirty-day mortality ($p = 0.33$), postoperative MI ($p = 0.342$), postoperative CVA ($p = 0.39$), re-exploration for bleeding ($p = 0.96$), requirement for blood transfusion which is higher in on-pump group (77.42% vs 94.83%, $p = 0.06$), atrial fibrillation ($p = 0.50$), and DSWI ($p = 0.70$) were comparable between the two groups (Table 3).

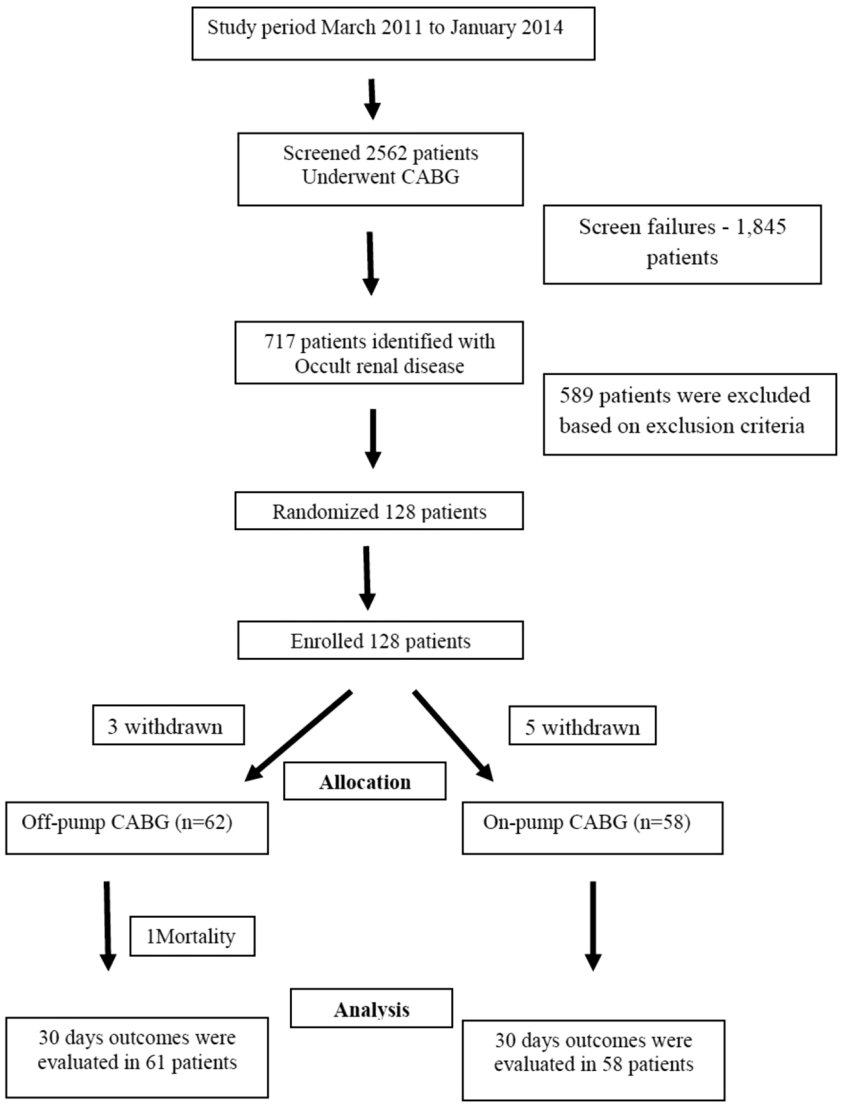


Fig. 1 Study flow chart. CABG: coronary artery bypass grafting

The serum creatinine and GFR were comparable between the groups preoperatively ($p = 0.34$, $p = 0.11$) as well as on 5th postoperative day ($p = 0.809$, $p = 0.419$). However, on 1st postoperative day, a statistically significant rise in serum creatinine (by 9.92% in off-pump and 15.45% in on-pump, $p = 0.02$) and a fall in GFR (by 0.71% in off-pump and 11.8% in on-pump, $p = 0.007$) were observed in on-pump group (Table 4).

Discussion

Earlier studies demonstrated that occult renal disease is associated with higher morbidity and mortality in patients undergoing coronary artery bypass grafting compared to patients with normal renal function [10, 16]. Najafi et al. demonstrated by multivariable logistic regression analysis that patients with occult renal insufficiency were at higher risk for mortality (odds ratio = 2.59; 95% confidence interval (CI), 1.15–5.86; $p = 0.022$) and prolonged hospital stay (> 7 days) (odds ratio = 1.30; 95% CI, 1.08–1.57; $p = 0.005$) [17]. Sajja et al. evaluated the need for postoperative dialysis in patients undergoing off-pump CABG (OPCAB) in various stages of renal dysfunction and demonstrated that patients with low preoperative GFR (stages 3 and 4, $p = 0.0001$) were at an increased risk for postoperative dialysis [18]. Miceli et al. found that ORD was associated with doubling the risk of death and increased postoperative renal impairment needing dialysis. They also reported ORD increases the risk of stroke, arrhythmia, and length of hospital stay, but there was no significant relationship between ORD and the risk of postoperative myocardial infarction [10]. Marui et al. observed that occult renal impairment was an independent risk factor for early and late deaths and major adverse cardiovascular events in patients undergoing CABG with impaired GFR associated with normal

Table 1 Analysis of demographics and comorbidities between off-pump and on-pump groups

Variables		Off-pump CABG ($n = 62$)		On-pump CABG ($n = 58$)		p value
		No. of patients	%	No. of patients	%	
Age (years) (mean ± SD)		61.88 ± 6.15		61.27 ± 6.70		0.60
Gender	Female	20	32.26	20	34.48	0.79
	Male	42	67.74	38	65.52	
Hypertension	Yes	52	83.87	45	77.59	0.38
	No	10	16.13	13	22.41	
Hyperlipidemia	Yes	15	24.19	16	27.59	0.67
	No	47	75.81	42	72.41	
Diabetes mellitus	Yes	42	67.74	37	63.79	0.64
	No	20	32.26	21	36.21	
Smoking	Yes	16	25.81	15	25.86	0.99
	No	46	74.19	43	74.14	
LV function	Mild-to-moderate LV dysfunction	12	19.35	17	29.31	0.28
	Normal LV function	50	80.64	41	70.68	
Prior CVA	Yes	2	3.23	3	5.17	0.67*
	No	60	96.77	55	94.83	
Prior MI	Yes	10	16.13	11	18.97	0.68
	No	52	83.87	47	81.03	
Prior PTCA	Yes	9	14.52	11	18.97	0.31
	No	53	85.48	53	91.38	

*Fisher exact test was used

CABG, coronary artery bypass grafting; *LVEF*, left ventricular ejection fraction; *CVA*, cerebrovascular accident; *MI*, myocardial infarction; *PTCA*, percutaneous transluminal coronary angioplasty; *SD*, standard deviation

serum creatinine levels, and recommended more accurate evaluation of renal function through a combination of serum creatinine and estimated GFR [16]. In an observational study in patients with preoperative normal renal function, it was demonstrated that patients undergoing CABG using off-pump technique had better preservation of renal function compared to patients undergoing on-pump technique [19]. Sajja et al. reported a randomized study in patients with non-dialysis-dependent renal insufficiency undergoing coronary artery bypass grafting; off-pump technique preserves renal function better than on-pump technique [9]. There are no studies reported whether the outcomes are similar or different between the off-pump and on-pump technique in patients undergoing coronary artery bypass grafting with occult renal disease [20]. Probably, this is the first randomized study that observed the impact of

Table 2 Intraoperative variables between off-pump and on-pump groups

Variables		Off-pump CABG ($n = 62$)		On-pump CABG ($n = 58$)		p value
		No. of patients	%	No of patients	%	
Conversion	Yes	0	0.00	2	3.45	0.23*
	No	62	100.00	56	96.55	
No of grafts (mean ± SD)		3.14 ± 0.74		3.25 ± 0.63		0.38
Ventilation duration (hours) (mean ± SD)		5.47 ± 7.96		6.45 ± 4.49		0.41
ICD Drain (ml) (mean ± SD)		309.67 ± 158.06		315.68 ± 208.99		0.85
Blood transfusion	Yes	48	77.42	55	94.83	0.006
	No	14	22.58	3	5.17	
IABP	Yes	0	0.00	2	3.45	0.23*
	No	62	100.00	56	96.55	

In on-pump CABG, means of CPB time (min) and cross clamp time (min) were 82.74 ± 29.48 and 47.39 ± 19.12 respectively

*Fisher exact test was used

CABG, coronary artery bypass grafting; *CPB*, cardiopulmonary bypass; *ICD*, inter coastal drain; *SD*, standard deviation

Table 3 Primary and secondary outcomes between off-pump and on-pump groups

Variables		Off-pump CABG ($n = 62$)		On-pump CABG ($n = 58$)		p value
		No of patients	%	No of patients	%	
Postoperative AKI	Yes	10	16.13	12	20.69	0.51
	No	52	83.87	46	79.31	
Postoperative AKI requiring renal replacement therapy	Yes	3	4.84	0	0	0.08
	No	59	95.16	58	100.0	
Mortality	Yes	1	1.61	0	0.00	0.33
	No	61	98.39	58	100.00	
Postoperative MI	Yes	3	4.84	1	1.72	0.34
	No	59	95.16	57	98.28	
Stroke	Yes	2	3.23	2	3.45	1.00*
	No	60	96.77	56	96.55	
Re-exploration	Yes	1	1.61	1	1.72	0.96
	No	61	98.39	57	98.28	
Atrial fibrillation	Yes	8	12.90	10	17.24	0.50
	No	54	87.10	48	82.76	
DSWI	Yes	3	4.84	2	3.45	0.70
	No	59	95.16	56	96.55	

*Fisher exact test was used

CABG, coronary artery bypass grafting; *AKI*, acute kidney injury; *MI*, myocardial infarction; *DSWI*, deep sternal wound infection

occult renal disease on the outcomes of off-pump and on-pump CABG. In this study, we observed that in patients with occult renal disease, there was no significant difference in the outcomes of postoperative AKI and requirement for RRT at 30 days. In addition, there was no statistically significant difference in the secondary outcomes at 30 days observed, which include mortality, postoperative myocardial infarction, stroke, or acute kidney injury requiring renal replacement therapy between off-pump and on-pump CABG patients with occult renal disease. Although there was a significant fall in GFR in the on-pump group on the postoperative day 1, the difference became statistically insignificant on the 5th postoperative day.

Study limitations

Our study cohort includes only low-risk patients undergoing CABG.

Conclusions

The incidence of postoperative AKI (stage I) was similar between off-pump and on-pump groups. No significant difference was observed in major adverse cardiac and cerebrovascular events and patients requiring renal replacement therapy between the groups. In patients with occult kidney disease,

Table 4 Trends in serum creatinine and GFR between off-pump and on-pump groups

Variables	Off-pump CABG ($n = 62$)	On-pump CABG ($n = 58$)	p value
Preoperative creatinine (mg/dl) (mean ± SD)	1.21 ± 0.11	1.23 ± 0.07	0.34
Preoperative GFR (ml/min/1.73 m^2) (mean ± SD)	53.19 ± 6.41	54.93 ± 5.42	0.11
Creatinine on day 1 (mg/dl) (mean ± SD)	1.33 ± 0.18	1.42 ± 0.21	0.02
GFR on day 1 (ml/min/1.73 m^2) (mean ± SD)	52.81 ± 9.42	48.45 ± 7.82	0.007
Creatinine on day 5 (mg/dl) (mean ± SD)	1.24 ± 0.31	1.25 ± 0.20	0.80
GFR on day 5 (ml/min/1.73 m^2) (mean ± SD)	57.24 ± 11.41	55.65 ± 10.02	0.41

CABG, coronary artery bypass surgery; *SD*, standard deviation; *GFR*, glomerular filtration rate;

our study demonstrated that on-pump CABG is associated with a significantly lower GFR and significantly higher serum creatinine on postoperative day 1 which return to baseline by postoperative day 5.

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Compliance with ethical standards

This study complies with the principles of the Declaration of Helsinki and was approved by the institutional ethics committee, and informed consent was obtained from all the patients.

Conflict of interest The authors declare that they have no conflict of interest.

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Discussant:

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Question 1. What is the probable mechanism you think, by which on-pump CABG caused increase in serum creatinine and decrease in GFR on first post operative day?

Response: On-pump CABG is associated with hemodynamic disturbances at the level of arterial blood supply to the kidneys due to inflammatory, immunological, neurohumoral and mechanical factors. The hemodilution associated with cardiopulmonary bypass and non-pulsatile flow may be responsible for rise in serum creatinine.

Question 2: What is that factor which contributed to the upward trend of renal replacement therapy in post op AKI in off-pump CABG, which is not seen in on-pump group?

Response: The upward trend of renal replacement therapy in patients of off-pump CABG appears to be unrelated to the technique of off-pump or on-pump CABG. Out of 3 patients who required RRT, one patient had complete heart block with hypotension, second patient had cardiac tamponade and third patient had sepsis.

Question 3. Have you deduced any risk factors for developing AKI in patients with borderline GFR which can help in taking the precautionary measures to prevent it?

Response: Most of these patients with GFR <60 mL/min/1.73m2 had preoperative nephrology consultation where Angiotensin-converting enzyme (ACE) inhibitors and Angiotensin II receptor blockers (ARBs) were withheld , albumin was transfused in patients with hypoalbuminemia and surgery was delayed for 24 to 72 hours after coronary angiography . The duration of CPB time did not differ significantly between the patients who developed AKI and who did not. However, the mean pump time was lower and is less than 90min.

Question 4. From your table we can see the on-pump group required no renal replacement therapy in spite of higher number of AKI. What is the reason? Did they improve?

Response: In the on-pump group less severe AKI (stage 1) occurred. All of them improved postoperatively and creatinine returned to baseline at the time of discharge.

Question 5. From your consort diagram we can see there is no attrition in number of patients after allocation to the groups. That's a very efficient conduct of a RCT. We have observed that there is high rate of attrition in randomized trials in cardiac surgery due to multiple factors. Please elaborate on the methods you used to prevent the attrition?

Response: There was no attrition in this study due to small number of patients (120) , shorter duration of study (less than 6 weeks) and enrollment of local patients who were willing to come back for the follow up.

Question 6. Considering the renal insult in occult group by coronary bypass surgery, can we generalize the concept to other organs like hepatic failure in borderline groups? Or there is renal specific mechanism involved in these patients?

Response: Ischemic hepatitis is defined as rapid and transient increase in serum transaminase levels more than 8 times of normal. There is no definition available for occult ischemic liver disease. In contrast to kidney, liver has dual blood supply from portal vein (75%) and hepatic artery (25%) and liver is less susceptible to ischemic injury. However, a mild increase in transaminase levels, less than 8 times of normal, can still be commonly found in studies in both off-pump and on-pump techniques.

Question 7. Is there any co-relation between diabetes mellitus, hypertension, LV dysfunction and prior PCI with intra-venous contrast and occurrence of AKI?

Response: The AKI is independent of diabetes mellitus, hypertension, prior PCI and LV dysfunction (mild to moderate).