

## Original Article

# Early Outcome of Off-Pump Versus Conventional Coronary Artery Bypass Grafting Surgery in Patients with Multivessel Coronary Artery Disease in a Specialized center in Bangladesh

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**Key Words :**  
IHD, Coronary artery bypass surgery, Bangladesh.

### Abstract:

**Background:** Both off-pump (OPCAB) and on pump arrest heart coronary artery bypass surgery (CABG) are frequently performed in department of cardiac surgery, NICVD, Dhaka, Bangladesh. Both types of procedures have advantages and disadvantages. This study was conducted to analyze early post-operative outcome following both types of CABG on patients with multivessel coronary artery disease.

**Methods:** Between 1<sup>st</sup> September 2019 to 28<sup>th</sup> February 2021, a cross-sectional study was performed with total 60 patients. 30 patients underwent Off Pump coronary artery bypass grafting (OPCAB)(Group A) and 30 patients underwent Conventional Coronary Artery Bypass (CCAB) (Group B) surgery. Preoperative, peroperative and post-operative variables were recorded and analyzed with appropriate statistical tools and  $p \leq 0.05$  considered statistically significant.

**Results:** Fifty-five male i.e., 91.67% and five female i.e., 8.33% of total patients were participated in this study. Mostly were within forty-five to sixty-four years age group. Preoperative risk factors, family history and drug history had no significant difference ( $p > 0.05$ ). Mean  $\pm$  SD number of bypass conduits given in each group almost similar and no statistically significant arrhythmia in terms of atrial fibrillation (AF), ventricular tachycardia (VT) and premature ventricular contraction (PVC) were found preoperatively ( $p > 0.05$ ). New onset of early post-operative ECG changes was found in 3 patients of group A and 9 in group B (10 % Vs. 30%). AF and PVC found in group B significantly ( $p < 0.05$ ) higher than group A. Immediate post-operative troponin I was higher in group B ( $p = 0.001$ ). Mean  $\pm$  SD duration of mechanical ventilation, inotropic supports, ICU stay, bleeding and blood transfusion and serum creatinine were significantly higher in group B ( $p < 0.05$ ). Overall immediate and follow up post-operative morbidities were higher in group B than A ( $p < 0.05$ ).

**Conclusion:** Though on pump arrest heart CABG still stands gold standard, in our study we found OPCAB is better than conventional method.

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### Introduction

Multivessel off-pump coronary artery bypass (OPCAB) surgery has been made possible by the development of innovative techniques and various stabilization systems.<sup>1</sup> Multivessel OPCAB operations have been shown to reduce perioperative morbidity, transfusion requirement, and postoperative length of stay, especially in

high-risk patients, including patients aged 70 years and older.<sup>2,3</sup>

The OPCAB technique was developed with specific purpose of reducing mortality and morbidity in high-risk patients.<sup>4</sup> The shorter operating time in OPCAB group is probably because of the shorter time required for haemostasis and no time spent

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on cannulation, managing cardiac arrest and rewarming from hypothermia during CPB. There is also less intra-operative and post-operative blood loss, a lower incidence of re-exploration for bleeding, a smaller transfusion volume and lower incidence of transfusion related complications.<sup>5</sup> The shorter ICU stay and ventilation time in the OPCAB group may be related to low incidence of the pulmonary dysfunction that occurs after CPB. Glomerular filtration rate and renal tubular function are better protected by OPCAB group than by conventional CABG.<sup>2</sup>

For several decades, conventional CABG (CCAB) surgery done in arrested heart was regarded as the standard of care for Multivessel disease in the patients eligible for surgical intervention.<sup>5</sup> Indeed, CCAB in presence of significantly diseased LMS coronary artery is likely to pose many challenges and are likely to become hemodynamically unstable at time of induction and cardiac manipulation during surgery.<sup>7</sup> However, this technique is linked to several side effects mostly due to use of aortic cross clamp, cardioplegia, and cardiopulmonary bypass. Contacts of blood components with the artificial surfaces of bypass circuit, aortic cross-clamping and reperfusion injury are considered the main causative factors of inflammatory response following cardiac surgery.<sup>6,8</sup>

An extensive literature search reveals that CCAB causes more complete revascularization as compared to OPCAB. Ivanov et al.<sup>8</sup> showed that a fewer amount of distal anastomosis was formed during off-pump coronary artery bypass surgeries as compared to on-pump procedures (2.6+/-1 to 3.1+/-1,  $p < 0.001$ ). Due to incomplete revascularization, Locker et al.<sup>10</sup> have reported that patients requiring more than 3 grafts are more likely to be treated on-pump.

Incomplete revascularization also leads to increased repeat procedures. Hence OPCAB patients have higher rates of repeat revascularizations as compared to CCAB patients.<sup>9</sup> One study noted this difference to be quite stark when the calculated hazard ratio of OPCAB patients getting repeat procedures as compared to CCAB.<sup>11</sup>

When studies of higher quality were analyzed, the OPCAB method still superior to the CCAB. There

are also potential economic benefits including reduced postoperative patient instability and faster recovery rate, reduced use of vasoactive drugs, less need for blood products and cost-effective resource utilization.<sup>8</sup> All the remaining morbidity outcomes such as atrial fibrillation, acute renal failure, re-operation and myocardial infarction showed just a trend towards favouring OPCAB surgery.<sup>12</sup> Different studies have compared early mortality between OPCAB and Conventional CABG for Multivessel disease, the rates for OPCAB surgery range from 0% to 1.8% for conventional CABG surgery between 2.6% and 5%.<sup>13</sup>

### Methods:

It was a cross-sectional study conducted in the Department of Cardiac Surgery, National Institute of Cardiovascular Diseases (NICVD), Sher-e-Bangla Nagar, Dhaka, Bangladesh from 1<sup>st</sup> September 2019 to 28<sup>th</sup> February 2021. Patients admitted in the Dept. of Cardiac Surgery at NICVD for CABG. Patients admitted in the department of cardiac surgery at NICVD with multivessel coronary artery disease for coronary artery bypass surgery were included. Total 60 samples were taken. Each group contained 30 samples. Group A = 30 patients with multivessel disease underwent OPCAB. Group B = 30 patients with multivessel disease underwent CCAB. Median sternotomy and harvesting of LIMA. The LIMA was harvested using diathermy and a chest retractor on one side of the sternum was performed. At that time, saphenous vein or radial artery was harvested under direct vision. All the anastomoses were done manually by hand.

In Group A patients: The protocol for heparin Sodium administration will be 50 IU/Kg body weight before division of LIMA and supplemental doses of 3000 IU every 30 minutes until the last anastomoses were completed. The objective is to obtain an ACT greater than 300 seconds. Standard OPCAB surgery was performed mostly with the use of a deep pericardial suture placed in the posterior pericardium for retraction. A single monofilament suture was applied to the target vessel proximal to the anastomotic of the intracoronary shunt of a variable diameter. The Octopus Evolution Tissue Stabilizer (Medtronic, Inc, Minneapolis, MN) and Starfish was used for

each patient to stabilize the coronary segment.

In Group B patients: Before establishing CPB, patients received Heparin (300 IU/kg body weight) to maintain Kaolin ACT exceeding 480 seconds. Standard CCAB surgery was performed with a uniform approach using ascending aortic cannulation and two-stage venous cannulation. During that period, the mean arterial pressure target was set at 60 mmHg and body temperature was allowed to drift or set to a minimum of 32 °C. Intermittent cold blood cardioplegia (1:4 bloods to crystalloid with a maximal K<sup>+</sup> concentration of 22 mEq/l) was delivered ante-grade via the aortic root. Heparin was reversed by administering two-thirds dose of Protamine (0.75 mg protamine /100 IU Heparin) after completion of last anastomoses. Additional amount of protamine sulphate was given if ACT found above 120 seconds. In each patient, two/three soft 32FD mediastinal drain tube (retrocardiac/retrosternal/pleural) was placed after surgery to drain blood and air from the chest cavity. Additional chest tube might place according to the evolving need like one-sided opening of

pleura during surgery. Surgical hemostasis was achieved using standardized protocol. Perioperative fluid and blood products were administered as clinically indicated.

Statistical analysis was conducted using Statistical Package for Social Science (SPSS) version 26.0 for windows software. Comparisons between groups were made with Chi-Square test and Fisher's exact test for qualitative data whereas unpaired Student's t-test quantitative data. Observations were recorded as statistically significant if a p-value < 0.05.

### Results:

Among study population, most of the patients were within 45-54- and 55-64-years age group i.e., 18 (30%) and 19 (31.66%) in group A and B respectively. Out of 60 patients, 55 (91.67%) patients were male and 5 (8.33%) were female (Table I). The comparison of history of smoking, IHD/MI, hypertension, dyslipidemia and diabetes mellitus, in group A and B patients were statistically not significant (p>0.05) (Table II).

**Table-I**  
*Comparison of Age, Gender and BMI between two groups.*

Demographic Variables	Groups			p value
	Group Af (%) n=30	Group B f (%) n=30	Total f (%) n=60	
Age (years)				
35-44	7 (23.33)	6 (20)	13 (21.66)	B 0.874 NS
45-54	8 (26.67)	10 (33.33)	18 (30)	B 0.741 NS
55-64	10 (40)	9 (30)	19 (31.66)	B 0.742 NS
65-75	5 (16.67)	5 (16.67)	10 (16.66)	B 1.00 NS
Mean ± SD	55.17 ± 11.64	54.50 ± 10.50		A 0.908 NS
Gender				
Male	28 (93.33)	27 (90)	55 (91.67)	
Female	2 (6.67)	3 (10)	5 (8.33)	B 0.640 NS
BMI (kg/m <sup>2</sup> )				
Underweight	1 (3.30)	3 (10)	4 (6.66)	B 0.451 NS
Normal	16 (53.33)	15 (50)	31 (51.67)	B 0.785 NS
Over weight	11 (36.67)	8 (26.67)	19 (31.67)	B 0.464 NS
Obese	2 (6.67)	4 (13.33)	6 (10)	B 0.375 NS
Mean ± SD	23.10 ± 4.51	23.61 ± 5.38		A 0.846 NS

<sup>A</sup> t test was done to measure the level of significance.

<sup>B</sup> Chi-square test was done to measure the level of significance.

Figure within parenthesis indicates percentage.

f = Frequency, NS = Not significant, BMI = Body mass index.

Triple vessel disease (TVD) was the most frequent preoperative diagnosis in both groups A and B (Table III). New onset of AF was found in 2 (6.67%) patients of group A and 8 (26.67%) patients of group B. PVC developed in 3 (10%) and 9 (30%) patients of group A and B respectively. Two (6.67%) patients developed new onset of heart failure in group A and 3 (10%) developed in group B ( $p>0.05$ ) (Table IV). Mean  $\pm$  SD duration of inotropes used following surgery ( $55.48 \pm 9.22$  and  $68.10 \pm 9.37$  hours respectively), mean  $\pm$  SD duration of ICU stay ( $60.45 \pm 9.26$  and  $80.23 \pm 8.45$  days respectively). Mean  $\pm$  SD duration of ventilator used in group A and B were  $6.45 \pm 1.61$  and  $9.63 \pm 3.03$  respectively). Mean  $\pm$  SD amount of blood loss (ml) in 1<sup>st</sup> 24 hour of group A and B was  $125.48 \pm 40.55$ ml and  $320.25 \pm 150.45$  ml respectively. Also amount of Blood transfused among group A and B was  $100.88 \pm 20.25$  ml and  $288.58 \pm 120.25$  ml respectively (Table V).

Post-operative bleeding- incidence of post-operative Neuro-cognitive dysfunction was 1 (3.33%) in group A and 7 (23.33%) in group B. 4 (13.33%) patients of group B developed stroke, which was higher than group A. Pulmonary complications were found in 3 (10%) patients of group A and 8 (26.67%) patients of group B. 2 (6.66%) patients of group A and 8 (26.67%). But post-operative wound infection and re-exploration showed no statistically significant difference (p value is 0.688 and 0.604 respectively) (Table VI). Post-operative morbidity than in group A population 12 (40%) and 4 (13.33%) respectively). One patient died in group A and 2 patients died in group B (Table VII). Neurocognitive dysfunction improved in both group which was 0 (0%) in group A and 5 (16.67%) in group B. Similarly, stroke was reduced to 0 (0%) in group A and 4 (13.33%) in group B, Renal complications was 0 (0%) in group A and 5 (16.67%) in group B (Table VIII).

**Table-II**  
*Comparison of the preoperative clinical profile between two groups.*

Demographic Variables	Groups		p value
	Group A f (%) n=30	Group B f (%)n=30	
Personal history			
• Smoker	20 (66.67)	22 (73.33)	0.639 <sup>NS</sup>
Family history(IHD/CVA)	7 (23.33%)	9 (30%)	0.536
Medical history			
• IHD/MI	22 (73.33)	24 (80)	0.639 <sup>NS</sup>
• Dyslipidemia	18 (60)	20 (66.67)	0.798 <sup>NS</sup>
• HTN	09 (30)	17 (56.67)	0.066 <sup>NS</sup>
• DM	17 (56.67)	21 (70)	0.284 <sup>NS</sup>
Drug history			
• Anti-platelet	28 (93.33)	27 (90)	0.814 <sup>NS</sup>
• CCB	10 (10)	13 (43.33)	0.311 <sup>NS</sup>
• Statins	25 (83.33)	26 (86.67)	0.131 <sup>NS</sup>
• Diuretics	12 (40)	8 (26.67)	0.161 <sup>NS</sup>
• Beta-blockers	13 (43.33)	15 (50)	0.739 <sup>NS</sup>
• ARB/ACEI	21 (70)	23 (76.67)	0.639 <sup>NS</sup>
• OHD	12 (40)	13 (43.33)	0.737 <sup>NS</sup>
• Insulin	5 (16.67)	7 (23.33)	0.697 <sup>NS</sup>

Chi-square test was done to measure the level of significance.

Figure within parenthesis indicates percentage.

f = Frequency, NS = Not significant. IHD = Ischemic heart disease, CVA= Cerebro Vascular Accident, MI = Myocardial Infarction, PVD = Peripheral vessel disease, HTN = Hypertension, DM = Diabetes mellitus, CCB = Calcium channel blocker, ARB = Angiotensin receptor blocker, ACEI = Angiotensin converting enzyme inhibitors, OHD = Oral hypoglycemic drug.

**Table-III***Comparison of the preoperative diagnoses of patients by coronary angiogram between two groups.*

Preoperative investigations	Groups		p value
	Group A f (%) n=30	Group B f (%)n=30	
DVD	5 (16.67)	3 (10)	0.844 <sup>NS</sup>
TVD	17 (56.66)	19 (63.33)	
DVD LMD	2 (6.67)	3 (10)	
TVD LMD	6 (20)	5 (16.67)	

Chi-square test was done to measure the level of significance.

Figure within parenthesis indicates percentage.

f = Frequency, NS = Not significant.

**Table-IV***Comparison of the post-operative cardiac status between two groups.*

Post-operative complications	Groups		Total f (%) n=60	p value
	Group A f (%)n=30	Group B f (%) n=30		
ECG changes				
No	27 (90)	21 (70)	48((80)	
Yes	3 (10)	9 (30)	11(18.33)	<sup>A</sup> 0.031 <sup>s</sup>
LVEF (%) (Mean ± SD)	54.17±10.43	53.53±9.35		<sup>B</sup> 0.673 <sup>NS</sup>
New onset of arrhythmia				
AF	3 (10)	9 (30)	9(18.33)	<sup>A</sup> 0.032 <sup>s</sup>
VT	1(3.33)	2 (6.67)	3(5)	<sup>A</sup> 0.604 <sup>NS</sup>
PVC	2 (6.67)	8(26.67)	10(16.67)	<sup>A</sup> 0.041 <sup>s</sup>
New onset of heart failure	2(6.64)	3 (26.67)	5(8.33)	<sup>A</sup> 0.741 <sup>NS</sup>

<sup>B</sup> Unpaired t-test was done to measure the level of significance.

<sup>A</sup> Chi-square test was done to measure the level of significance.

Figure within parenthesis indicates percentage.

f = Frequency, NS = Not significant, AF= Atrial fibrillation, VT= Ventricular Tachycardia, PVC= Premature Ventricular Contraction, IABP= Intra-Aortic Balloon Pump.

**Table-V***Comparison of the post-operative outcomes between two groups.*

Post-operative outcomes	Groups		p value
	Group A f (%) n=30 Mean ± SD	Group B f (%) n=30 Mean ± SD	
Troponin I (ng/dL)	1.12 ± 0.64	3.36 ± 1.13	0.001 <sup>S</sup>
Duration of ventilator used (hours)	6.45 ± 1.61	9.63 ± 3.03	0.048 <sup>S</sup>
Duration of inotropes used (hours)	55.48 ± 9.22	68.10 ± 9.37	0.001 <sup>S</sup>
Duration of ICU stay (hours)	60.45 ± 9.26	80.23 ± 8.45	0.001 <sup>S</sup>
Bleeding within 1 <sup>st</sup> 24 hour (ml)	125.48 ± 40.55	320.25 ± 150.45	0.001 <sup>S</sup>
Blood transfusion (ml)	100.88 ± 20.25	288.58 ± 120.25	0.001 <sup>S</sup>
S. creatinine in 1 <sup>st</sup> POD (mg/dl)	1.28 ± 0.89	2.01 ± 0.93	0.043 <sup>S</sup>

**Table-VI**  
*Comparison of the post-operative complications between two groups.*

Post-operative complications	Groups		p value
	Group A f (%) n=30	Group B f (%)n=30	
Neuro-cognitive dysfunction	1 (3.33)	7 (23.33)	<sup>A</sup> 0.023 <sup>S</sup>
Stroke	0	4 (13.33)	<sup>A</sup> 0.038 <sup>S</sup>
Pulmonary complication	3 (10)	8 (26.67)	<sup>A</sup> 0.05 <sup>NS</sup>
Renal complication	2 (6.66)	8 (26.67)	<sup>A</sup> 0.023 <sup>S</sup>
Wound infection	1 (3.33)	2 (6.66)	<sup>A</sup> 0.688 <sup>NS</sup>
Re-exploration	1 (3.33)	2 (6.67)	<sup>A</sup> 0.604 <sup>NS</sup>
Hospital stays (days)			
≤10 days	20	12	
>10 days	10	18	
Mean ± SD	9.41 ± 2.22	10.56 ± 2.344	<sup>B</sup> 0.078 <sup>NS</sup>

<sup>B</sup> Unpaired t-test was done to measure the level of significance.

<sup>A</sup> Chi-Square Test was done to measure the level of significance.

Figure within parenthesis indicates percentage.

**Table-VII**  
*Comparison of the post-operative morbidity and mortality between two groups.*

Post-operative complications	Groups		Total f (%) n=60	p value
	Group A f (%)n=30	Group B f (%) n=30		
Morbidity				
Yes	4 (13.33)	12 (40)	16 (26.67)	0.001 <sup>S</sup>
No	26 (86.67)	18 (60)	44 (73.33)	
Total	30 (100%)	30 (100%)		
Mortality				
Yes	1 (3.33)	1 (3.33)	2 (3.33)	1.000 <sup>NS</sup>
No	29 (96.67)	29 (96.67)	58 (96.67)	
Total	30 (100%)	30 (100%)		

Chi-square test was done to measure the level of significance.

Figure within parenthesis indicates percentage.

f = Frequency, S = Significant, NS = Not significant.

**Table-VIII**  
*Comparison of the post-operative complications between two groups.*

Post-operative complications	Groups		p value
	Group A f (%) n=30	Group B f (%)n=30	
Neuro-cognitive dysfunction	0 (0)	5 (16.67)	0.020 <sup>S</sup>
Stroke	0 (0)	4 (13.33)	0.038 <sup>S</sup>
Pulmonary complication	1 (3.33)	4 (13.33)	0.161 <sup>NS</sup>
Renal complication	0 (0)	5 (16.67)	0.020 <sup>S</sup>
Wound infection	1 (3.33)	3 (10)	0.301 <sup>NS</sup>

Fisher's exact test was done to measure the level of significance.

Figure within parenthesis indicates percentage.

f = Frequency, S = Significant, NS = Not significant.

**Discussion:**

This comparative cross-sectional study was performed to assess the early postoperative outcome of off-pump versus conventional on-pump CABG in patients with multivessel coronary artery disease. Demographic and anthropometric variables were recorded and analyzed. There were no statistically significant differences. Mostly were between 45-54 years age group. Study conducted by Chang, Wang and Chang<sup>8</sup> was similar to our study.

We found 93% male in group A and 90% male in group B which is similar to study by Innocentiis and his colleagues study.<sup>14</sup>

Mean  $\pm$  SD BMI level of both groups had no significant difference ( $p > 0.05$ ). Meharwal and his colleagues<sup>12</sup> was found Mean  $\pm$  SD BMI of their study was  $24.60 \pm 45$ . In our study, mean  $\pm$  SD BMI was almost similar with this study.

The comparison of history of smoking, family history (IHD, CVA), past history of IHD/MI, hypertension, dyslipidemia and diabetes mellitus and drug history revealed no difference. Mean LVEF and presence of wall motion abnormality was similar in both groups. Innocentiis et al.,<sup>14</sup> conducted a study which support these findings.

Per-operative data were recorded and analyzed. Mean  $\pm$  SD number of bypass grafts given to both groups almost similar and had no statistically significant difference. But group B taken longer duration of surgery than group A. Events during surgery i.e., AF, VT and PVC also showed no statistically significant difference. Same types of findings were found by Rihal and his colleagues.<sup>15</sup>

Three (10%) patients of group A and 9 (30%) patients of group B showed immediate post-operative ECG changes as ST elevation, ST depression and T inversion. This changes between the groups were statistically significant. But LVEF (%) were almost similar between groups. New onset of AF was found in 9 patients PVC was found in 8 patients of group B, which was significantly higher than group A. New onset of heart failure and IABP requirement showed nothing significant difference between the groups. These findings are supported by study conducted by Lamy and his associates.<sup>16</sup>

Between group A and B, immediate post-operative Troponin-I level was  $1.12 \pm 0.64$  and  $3.36 \pm 1.13$

ng/dL respectively. Mean  $\pm$  SD duration of inotropes used following surgery ( $55.48 \pm 9.22$  and  $68.10 \pm 9.37$  hours respectively), mean  $\pm$  SD duration of ICU stay ( $60.45 \pm 9.26$  and  $80.23 \pm 8.45$  days respectively). Mean  $\pm$  SD duration of ventilator used in group A and B were  $6.45 \pm 1.61$  and  $9.63 \pm 3.03$  respectively). Mean  $\pm$  SD amount of blood loss (ml) in 1<sup>st</sup> 24 hour of group A and B was  $125.48 \pm 40.55$  ml and  $320.25 \pm 150.45$  ml respectively. Also amount of Blood transfused among group A and B was  $100.88 \pm 20.25$  ml and  $288.58 \pm 120.25$  ml respectively. Mean  $\pm$  SD level of serum creatinine (mg/dl) in 1<sup>st</sup> POD of group A and B was  $1.28 \pm 0.89$  and  $2.01 \pm 0.93$  respectively. This differences by mean of Troponin I (ng/dL), duration of ventilation, duration of inotropes used, ICU stay, bleeding within 1<sup>st</sup> 24 hour (ml), blood transfusion (ml) and serum creatinine level in 1<sup>st</sup> POD was statistically significant ( $p < 0.05$ ). Study conducted by Chang, Wang and Chang<sup>8</sup> supports our study.

This study shows patients of group B developed post-operative neurocognitive dysfunction which was significantly higher than group A. Three (6.66%) patients of group A and 8 (26.67%) patients of group B developed renal complications. Mean  $\pm$  SD duration of hospital stay from date of operation was slightly less in group A than group B which were  $9.41 \pm 2.22$  days and  $10.56 \pm 2.344$  but without statistical significance. Three (6.66%) patients of group A and 8 (26.67%) patients of group B developed renal complications. Between two groups, group B population had more frequency of post-operative morbidity than in group A population 12 (40%) and 4 (13.33%) respectively which was statistically significant. One patient died in group A and 2 patients died in group B which was statistically insignificant. Innocentiis and his associates conducted a study which is consistent with these findings.<sup>14</sup>

Innocentiis and his colleagues also studied follow-up after 1 months. Which found improved neurological, pulmonary and renal status of patients underwent OPCAB than conventional group. In our study, neurological and renal complications in group A was improved in all patients but presented on group B. although improved than immediate post-operative status, was statistically significant. Wound infection was

slightly higher than immediate post-operative period in both group but statistically insignificant.

### Conclusion:

This study concludes that, off-pump CABG is relatively better option for multivessel coronary artery disease than on-pump CABG in respect of LVEF% improvement, duration of ventilator and inotropic support; need for blood transfusion and ICU stay; post-operative renal, neurological, pulmonary and infectious complications. So, if patients fulfill the criteria, off-pump CABG can be performed as routine procedure for IHD with multivessel disease.

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### Conflict of Interest - None.

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