*Original Article*

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# Clinical and Angiographic Outcome of Coronary Artery Bypass Surgery with and without Cardiopulmonary Bypass: A Prospective Observational Study

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**Abstract**

*Objective:* The ongoing controversy regarding coronary surgery as to perform with or without using cardiopulmonary bypass has not come to a definite conclusion with quite difference between Indian and western scenario. Our objective was to perform a single center, single surgeon prospective observational study to compare clinical outcomes and graft patency in off-pump versus on-pump coronary artery bypass surgery (CABG), to evaluate the current perspective of Indian scenario. *Method:* 100 patients were selected and divided into two groups, 50 patients in each group. All surgical planning and patient management were standardized for both groups. Various preoperative demographics, intraoperative variables and postoperative outcomes were measured and compared. After one year, follow-up computed tomography (CT) coronary angiography was done to evaluate the graft patency in all patients of both the groups. *Results:* The number of grafts performed per patient was higher in on-pump group, (3.3 vs. 2.7) however the index of completeness of revascularization was similar in both groups. (96.5% vs. 94%, $p$ = NS). There were significant increase in re-explorations, bleeding, transfusions and hospital stay in on pump group. At one-year follow-up, 64 patients underwent CT coronary angiography. 67 of 86 grafts (77.90%) were in off pump group as compared with 86 of 110 grafts (78.1%) in on pump group were patent. All occluded grafts were saphenous vein conduits to coronary targets other than left anterior descending (LAD) territory. *Conclusion:* Off pump CABG can provide complete durable and cost effective revascularization comparable with on pump CABG when performed in well experienced hand without compromising completeness of revascularization.

**Keywords:** Coronary artery bypass surgery,cardio-pulmonary, Bypass, off pump surgery, graft patency.

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## Introduction

Despite increasing competition from percutaneous interventions and other novel methods of non-surgical coronary revascularization, coronary artery bypass grafting (CABG) remains the most definitive therapeutic modality for severe coronary artery disease.[1] Since introduction, CABG has been performed with cardio-pulmonary bypass (CPB),

on-pump CABG is referred to as 'conventional CABG. The use of CPB and cardioplegic arrest provides a more stable and bloodless operative field, but are associated with a systematic inflammatory response, increased red cell damage and stroke from manipulation and clamping of the ascending aorta.[2] With the use of modern stabilizers and intra-cardiac shunts, off-pump coronary surgery has become more accessible and technically feasible.[3]

There is an ongoing, controversial discussion on whether coronary bypass grafting surgery should be performed with or without cardiopulmonary bypass. There are no guidelines on myocardial revascularization, which provides a clear cut directive. Moreover, both strategies have distinct advantages and disadvantages of their own. The possible reasons are that high-quality studies have not comprehensively examined relevant patient outcomes and have enrolled a limited range of patients. Therefore, very few occasions, rare single centric, single surgeon studies in the literature were found. Therefore, we have undertaken a prospective observational study to compare clinical outcomes and graft patency in off-pump versus on-pump CABG, done by a single surgeon in a single center to evaluate the current perspective of the Indian scenario.[4]

## Materials and Methods

### *Study Design and Patients*

This was a prospective observational study, designed to compare the clinical outcome, completeness of revascularization and graft patency in unselected patients referred for elective, isolated, primary CABG assigned to undergo Off-Pump CABG (OPCAB) with a suction stabilizer or CABG with CPB at the surgeon's preference. The main efforts were to minimize variability, all procedures were performed by a single experienced surgeon at a single center (UNMICRC) and postoperative care was provided by the ICU team according to strict, unbiased, criteria-driven protocols.

The patients undergoing primary coronary artery bypass surgery were included as eligible criteria. All angiograms were reviewed and a surgical plan was documented. Exclusion criteria were indication for additional surgical procedures (e.g. concomitant mitral or aortic valve repair/ replacement, ventricular septal rupture repair, aneurysm repair, aortic procedure) stroke within the preceding six months, carotid-artery stenosis of more than 70 percent, poor left ventricular function, with an ejection fraction of less than 25 percent, history of complications after diagnostic angiography were documented.

Postoperative morbidity in terms of stroke, perioperative myocardial infarction, transient ischemic attack, and new-onset renal failure was recorded.[5,6,7,8] 30-day mortality was defined as death due to any cause during the hospital stay or within 30 days after the surgery.

A total of 100 patients were divided into two groups. Each group carried an equal number of patients ($n$ = 50). After approval by the institutional review board and ethical committee, patients were enrolled from October 2013. 100 patients completed enrollment in November 2014. During these 13 months, the operating surgeon performed primary, elective, isolated CABG on a total of 193 patients. 51% of the total eligible patients during this period were enrolled in the Study. Informed consent was taken from all the patients.

The on-pump CABG was depicted as group 1 and off-pump CABG was depicted as group 2.

### *Treatment and Procedures*

#### *Common for both the groups*

All patients had two arterial lines femoral and radial as per our protocol. Triple lumen catheter used in patients with EF >45% and a Pulmonary Artery (PA) catheter was used in patients with EF <45% for more invasive monitoring. Surgical access to the heart was through a median sternotomy in all cases. Fine monofilament Polypropylene suture (7-0) was used for all distal anastomoses and 6-0 monofilament suture for proximal anastomosis. A humidified oxygen blower was used to disperse blood from the anastomotic site during the construction of distal anastomoses in both groups. All patients received pedicled Left Internal Mammary Artery (LIMA) and reversed saphenous venous grafts without any sequential or jump grafts. No other conduits were used. Protamine was given to reverse heparin in a 1:1 ratio.

#### *Postoperative Protocol*

Postoperative ACT was maintained with heparin infusion for 24 hrs. Aspirin 150 mg was started 6 hours after the surgery, after ensuring minimal drain output. Dual antiplatelet with clopidogrel 75 mg once daily started from 2nd post-operative day.

*Follow up*

All patients were followed up after three months of the operation and then after one year and 5 years at that time they were scheduled to undergo CT coronary angiography. Adverse events and symptom status were recorded for all patients, including those who refused angiography during follow up. A qualified Radiologist who was unaware of the patients' original study assignments interpreted all angiograms.

### *Statistical analysis*

The statistical calculations were performed using SPSS software v 20.0 (Chicago, IL, USA). Continuous data were expressed as mean ± SD. Continuous variables data were compared using the student's t-test, whereas the chi-square test was used for the categorical data. The cut-off value of $p < 0.05$ was considered for statistical significance.

## Results

*Preoperative data:*

Out of the 100 cases studied, all the patient characteristics and basic demographic details in both the groups were comparable. There was a significant difference in the mean planned number of grafts 3.4 in group 1 vs. 2.9 in group 2, (P=0.004). The rest of all the variables were comparable between the two groups (Table 1).

*Intra-operative data:*

The number of grafts performed per patient was higher in group 1, (3.3 in group 1 and 2.7 in group 2) however the index of completeness of revascularization (number of grafts planned / number of grafts done x 100) was similar in both the groups. (96.5% in group 1 and 94% in group 2) ($p$ = NS) (Table 2).

*Immediate postoperative data:*

There was no *30-day mortality*. The re-exploration, blood loss, transfusion, hospital stay, duration of ventilation and arrhythmias were significantly higher in group 1. Perioperative myocardial infarction (MI), transient ischemic attack (TIA) and new onset of renal failure were not affected by either technique. In both groups, no patients had deep sternal infection (Table 3).

*1-year follow-up and quantitative coronary angiography:*

Out of a total of 100 patients, 3 expired (2 in group 2 and 1 in group 1) at the end of 1 year. Out of the 97 patients who were alive at 1 year, 64 (31 in group 2 and 33 in group 1, $p$ = NS) had CT coronary angiography done at a mean of 394.5 ± 12.3 days after surgery (group 1- 393.3: group 2- 396.8, $p$ = NS) (Table 4).

The late outcome of on pump and OPCABG are summarized in Table 5. There was no significant difference in both the groups in terms of survival, freedom from revascularization, myocardial infarction and major adverse cardiac and cerebrovascular events. 22 patients refused to consent for follow up angiography. They were evaluated for symptoms of ECG and echocardiography.

A total of 196 grafts were done in 64 patients including both on-pump and off-pump groups. Out of which 110 grafts were performed in group 1 and 86 grafts were performed in group 2. Overall, 77.9% of grafts were patent among OPCAB patients compared with 78.1% of the grafts among CABG with cardiopulmonary bypass patients ($p$ = 0.33 [Fisher exact], $p$ = 0.44 [generalized estimating equation]. Patency was similar between groups at 1 year among all arterial conduits, all venous conduits and among grafts to each region of the heart. 43 (21.93%) of 196 grafts studied were occluded at 1-year follow- up. Of these, 19 were

**Table 1:** Comparison of preoperative data

| Characteristics | Group 1 ($n$ = 50) | Group 2 ($n$ = 50) | $p$ Value |
|---|---|---|---|
| Age (year, mean ± SD) | 57.64 ± 7.93 | 55.09 ± 8.98 | 0.1355 |
| Sex (No. Male) | 41 | 43 | 0.7850 |
| DM (No. patients) | 17 | 16 | 1.0000 |
| HTN (No. patients) | 28 | 25 | 0.6886 |
| COPD (No. patients) | 6 | 4 | 0.7389 |
| Smoking (No. patients) | 19 | 18 | 1.0000 |

| Characteristics | Group 1 ($n$ = 50) | Group 2 ($n$ = 50) | $p$ Value |
|---|---|---|---|
| Baseline EF (mean ± SD) | 44.8 ± 8.82 | 43.8 ± 10.27 | 0.6026 |
| >45% (No. patients) | 24 | 21 | 0.6877 |
| 31-45 % (No. patients) | 21 | 23 | 0.8403 |
| 25 -30 % (No. patients) | 5 | 6 | 1.0000 |
| Previous MI (No. patients) | 18 | 11 | 0.1861 |
| Previous CVA (No. patients) | 0 | 0 | – |
| Previous TIA (No. patients) | 0 | 1 | 1.0000 |
| Previous angioplasty (No. patients) | 6 | 9 | 0.5754 |
| Previous PVD (No. patients) | 1 | 3 | 0.6098 |
| Renal failure (No. patients) | 0 | 0 | – |
| NYHA class III / IV (No. patients) | 1 | 0 | – |
| CCS class III or IV (No. patients) | 9 | 6 | 0.5754 |
| Serum. Creatinine mg/dl (mean± SD) | 0.79 ± 0.17 | 0.72 ± 0.16 | 0.365 |
| Coronary involvement (No. patients) | | | |
| One-vessel disease | 1 | 3 | 0.6098 |
| Two-vessel disease | 11 | 16 | 0.3676 |
| Three-vessel disease | 38 | 31 | 0.2838 |
| Vessels Involved (No. patients) | | | |
| LMCA | 21 | 18 | 0.6818 |
| LAD (territory) | 50 | 50 | 0.9203 |
| LCX (territory) | 43 | 38 | 0.3079 |
| RCA (territory) | 40 | 37 | 0.6349 |

BMI: Basal metabolic index, DM: Diabetes mellitus, HTN: Hypertension, COPD: Chronic obstructive pulmonary disease, EF: Ejection fraction, MI: Myocardial infarction, CVA: Cerebrovascular accident, TIA: Transient ischemic attack, PVD: Peripheral vascular disease, NYHA: New York Heart Association, CCS: Canadian Cardiovascular Society, LMCA: Left Main Coronary Artery, LAD: Left coronary artery, LCX: Left circumflex artery, RCA: Right coronary artery

**Table 2:** Intra-operative Details

| Characteristics | Group 1 ($n$ = 50) | Group 2 ($n$ = 50) | $p$ Value |
|---|---|---|---|
| No. of Grafts per patient done | 3.32 ± 0.82 | 2.76 ± 0.78 | 0.0007 |
| No. of Grafts per patient planned | 3.43 ± 0.89 | 2.93 ± 0.91 | 0.0066 |
| Completeness of Revascularization | 96.7% | 94.2% | - |
| Total Number of Grafts | 166 | 138 | - |
| No. of Distal Anastomosis (No. patients) | | | |
| 1 | 1 | 4 | 0.3588 |
| 2 | 6 | 15 | 0.0495 |
| 3 | 21 | 20 | 1.0000 |
| 4 | 20 | 11 | 0.0837 |
| 5 | 2 | 0 | 0.4751 |
| LAD & branches Grafted (no of grafts) | 50 | 48 | - |
| LCX & branches Grafted (no of grafts) | 74 | 56 | - |
| RCA & branches Grafted (no of grafts) | 42 | 34 | - |
| Endartectomy | 11 | 8 | - |
| CPB Time (minutes) (Mean ± SD) | 93.34 ± 24.36 | - | - |
| AOX Time (minutes) (Mean ± SD)+ | 53.44 ± 16.26 | - | - |

LAD: Left coronary artery, LCX: Left circumflex artery, RCA: Right coronary artery, CPB; Cardio Pulmonary Bypass, AOX: Aortic Cross Clamp time

**Table 3:** Postoperative data

| Characteristics | On pump CABG (*n* = 50) | Off Pump CABG (*n* = 50) | *p* Value |
|---|---|---|---|
| **Packed cells** | 27 | 12 | 0.004 |
| **Clotting Products** | 29 | 11 | 0.002 |
| **AF** | 6 | 2 | 0.2688 |
| **VF** | 7 | 1 | 0.0653 |
| **Ventilation Hours** (Mean ± SD) | 10.26 ± 15.11 | 4.96 ± 3.46 | 0.0175 |
| **ICU Stay in days** (Mean ± SD) | 5 ± 2.20 | 3.44 ± 1.04 | <0.0001 |
| **Hospital Stay in days** (Mean ± SD) | 8.76 ± 2.70 | 6.44 ± 1.50 | 0.002 |
| **Drainage output (ml)** (Mean ± SD) | 554.6 ± 402.68 | 274.1 ± 68.68 | <0.0001 |
| Re-exploration | 3 | 1 | 0.2085 |
| **Neurological Cx** (No. patients) | | | |
| Permanent Stroke | 0 | 0 | - |
| TIA | 2 | 0 | - |
| **Renal Cx** (No. patients) | | | |
| New Renal Failure | 1 | 0 | - |
| New Dialysis | 0 | 0 | - |
| **Infections** (No. patients) | | | |
| Superficial Sternal | 4 | 2 | 0.6737 |
| Deep Sternal | 0 | 0 | - |
| Harvest Conduit Site | 3 | 2 | 1.0000 |
| **Pulmonary Cx** (No. patients) | | | |
| Pleural Effusions requiring Thoracentesis | 5 | 2 | 0.4331 |
| Postoperative EF (Mean ± SD) | 47.3 ± 6.72 | 44.5 ± 8.26 | 0.0660 |

AF: Atrial fibrillation, VF: Ventricular fibrillation, ICU: Intensive care unit, TIA: Transient ischemic attack, EF: Ejection fraction

**Table 4:** Angiographic outcomes 1-year post-operatively

| Variables | On pump CABG (*n* = 33) | Off Pump CABG (*n* = 31) | *p* Value |
|---|---|---|---|
| **Patency rate territory wise (No of grafts patent/total no of grafts)** | | | |
| Overall | 78.1% (86 / 110) | 67 / 86 (77.90%) | 0.8983 |
| LAD & branches | 97.4% (38 / 39) | 33 / 34 (97.22%) | 0.5351 |
| LCX & branches | 30 / 40 (75%) | 18 / 30 (60.0%) | 0.2812 |
| RCA & branches | 18 / 31 (58.06%) | 16 / 22 (72.72%) | 0.1874 |
| **Patency rate conduit wise (No of grafts patent/total no of grafts)** | | | |
| Overall | 78.1% (86/110) | 77.90% (67/86) | 0.8983 |
| LIMA | 100% (33/33) | 100% (31/31) | 1.0000 |
| Saphenous vein | 68.83% (53/77) | 65.45% (36/55) | 0.8261 |
| **Site of blockage in blocked conduits** | | | |
| Site of Blockage | No. of blocked conduits (n=43) | | |
| | On Pump (n=24) | Off Pump (n=19) | |
| Proximal anastomotic site (n %) | 05 (20.8%) | 04 (21%) | 0.7189 |
| Conduit itself (n %) | 14 (58.4%) | 12 (63.2%) | 0.9942 |
| Distal anastomotic site (n %) | 05 (20.8%) | 03 (15.8%) | 0.9780 |

LAD: Left coronary artery, LCX: Left circumflex artery, RCA: Right coronary artery, LIMA: Left internal mammary artery

**Table 5:** Follow up 1 to 5 years outcome.

| Variables | Group 1 (*n* = 50) | Group 2 (*n* = 50) | *p* Value |
|---|---|---|---|
| **Survival** | | | |
| 1 Year (N %) | 49 (98) | 48 (96) | 1.0000 |
| 5 Year (N %) | 45 (90) | 44 (88) | 1.0000 |
| **Freedom from revascularization** | | | |
| 1 Year (N %) | 45 (90) | 43 (86) | 0.7583 |

| Variables | Group 1 ($n$ = 50) | Group 2 ($n$ = 50) | $p$ Value |
|---|---|---|---|
| 5 Year (N %) | 38 (76) | 36 (72) | 0.8197 |
| **Event of Myocardial infarction** | | | |
| 1 Year (N %) | 43 (86) | 42 (84) | 1.0000 |
| 5 Year (N %) | 37 (74) | 35 (70) | 0.8238 |
| **MACCE** | | | |
| 1 Year (N %) | 36 (72) | 35 (70) | 0.7432 |
| 5 Year (N %) | 32 (64) | 31 (62) | 1.0000 |

in group 2 patients and 24 were in group 1. Out of these 43 occluded grafts, all were saphenous vein conduits to coronary targets other than LAD territory, while all left internal mammary artery (LIMA) grafts were well flowing in both groups. There was no significant difference in the site of occlusion of grafts (Table 4).

## Discussion

This observational study reports the outcome from a single surgeon practice. Of the 100 patients included in the study OPCABG and the on-pump technique was used in 50 patients each. It was found that the mean [SD] number of grafts performed per patient (group 1: 3.32 [0.82]; group 2: 2.76 [0.78]) were slightly higher in group 1, but the number of grafts performed per number of grafts intended (index of completeness of revascularization)[9] were similar between groups (group 1: 0.96 [0.09]; group 2: 0.94 [0.18]). Thus, even the OPCAB achieved complete revascularization when applied to unselected patients, avoiding the documented negative consequences of incomplete revascularization as shown in previous studies.[10-13]

The average size of the coronary artery was larger in most of the studies compared to our study (2.1 mm in the study by Khan et al.[12] as compared to 1.55 mm in our study) which was significantly lower in our case. The native vessel quality is also an independent predictor of graft patency, especially venous graft patency. In a study by Khan et al, they showed that only 10% of total vessels had poor quality, while 65% of the vessels were of good quality. In our study, 28% of the vessels had poor vessel quality (plaque, calcification or diameter of < 1.25 mm), while only 45% had good vessel quality, which was significantly lower than the compared Khan et al data.[12]

It was found that the patency rate at 1-year follow-up was similar between the two groups. Patency for arterial conduits was excellent and 100% in both the groups. Left internal thoracic artery (LIMA) was used as an arterial conduit in all patients of both the groups; all grafted to the Left Anterior Descending (LAD) artery, with 100% patency in LAD territory. The rest of all grafts were saphenous venous grafts in all patients of both the groups. Overall graft patency was 77.9% in the off-pump group and 79.1% in the on-pump group, which were similar in both the groups. The overall graft patency was however low as compared to previous studies but it was similar in both the groups and not significantly low in OPCAB which were comparable to various studies and literature.[11,12,14,15]

The venous graft patency was significantly reduced in our study as compared to other studies. (68.83% in group 1 and 65.45% in group 2). The phenomenon of increased pro-coagulant activity after OPCAB[16,17] has been invoked to explain the isolated reports of diminished vein graft patency after OPCAB.[18-20] Importantly, in the present study similar patency of saphenous vein grafts was reduced between the groups which were comparable with study of Magee, et al, in his study he has found saphenous vein failure rate was 25% in both groups.[18] In our study, poor venous graft patency might be due to poor target vessels and the diffuse nature of the native coronary disease. The quality of the target arterial wall directly correlates with graft failure rates. This is the most accurate reflection of our current practice and difficulties faced by the expert surgeons also to operate in this era.

We use CT angiography as a tool for follow up evaluation. CT angiography has good diagnostic accuracy to assess graft patency with a sensitivity of 96% and specificity of 95%.[21]

Unlike other studies we did not see any significant differences in stroke in either group. Also similar to other studies no significant difference in 30 days mortality, pulmonary complications and wound infection were observed in our study.[22-25]

While lack of experience and not having a standard protocol were concerns in previous

studies our study was a single surgeon practice with significant OPCAB experience.

### *Limitation of study*

The major limitation of our study is the limited sample size. The major factor for the limited initial sample size is the economic burden on the institute for performing the CT Angiogram of all the patients. Another limitation in the study was that we could enroll only 64% of patients for angiography after a 1-year follow-up though our follow up is more than 95%. Although there was no systematic difference between the 2 groups regarding lack of 1-year angiography, the possibility of selection biases in such cases cannot be excluded.

## Conclusion

These were an observational study that demonstrated off-pump CABG may provide complete revascularization which is durable, cost-effective and lesser adverse events but with similar graft patency at one year compared to CABG with cardiopulmonary bypass when performed on unselected patients undergoing elective, isolated CABG inexperienced hand.

However, a larger number of a multicenter trial of off-pump coronary artery bypass (OPCAB) compared with CABG with cardiopulmonary bypass is needed to evaluate the results to better clarify the role of OPCAB in the routine care of patients with multi-vessel coronary artery disease.

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