ORIGINAL ARTICLE

Off-pump versus on-pump coronary artery bypass grafting in patients with left main coronary artery disease: A randomized controlled trial

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Abstract

Objective: To compare the outcome of off-pump and on-pump coronary artery bypass graft surgery in patients with left main coronary artery disease.

Method: The randomised, controlled, prospective, multicentric study was conducted in 2020 during the period from January 2020 to December 2020 at Kafrelsheikh University Hospital, International Cardiac Centre and Alexandria New Medical Centre, Egypt, and comprised patients with left main coronary artery disease who underwent coronary artery bypass graft surgery. The patients were randomised to on-pump surgery group I (Control Group) and off-pump surgery group II(Interventional Group). All patients were assessed pre-operatively for the presence of comorbid conditions and post-operatively for myocardial infarction, acute kidney injury, pneumonia, sternal dehiscence and 3-month mortality. Data was analysed using SPSS 20.

Results: Of the 60 patients, 44(73.3%) were men and 16(26.6%) were women. The overall mean age was 66.4±9.2 years. There were 30(50%) patients in each of the two groups. There were 2(6.7%) cases of myocardial infarction in group I and 1(3.3%) in group II. There was 1(3.3%) case of acute kidney injury in group I and none in group II. There were 3(10%) cases of pneumonia in group 1 compared to 1(3.3%) in group II. There was 1(3.3%) case of sternal dehiscence in group I and none in group II. Mortality at 3 months was 2(6.7%) in group I and 1(3.3%) in group II. There was no significant difference with respect to outcome between the groups ($p>0.05$).

Conclusion: Off-pump coronary artery bypass graft surgery was found to be efficient and non-inferior to on-pump procedure in patients with left main coronary artery disease.

Keywords: Coronary artery, Bypass, Myocardial infarction, Kidney, Diabetes, Myocardium, Pneumonia.

RCT registration: The RCT was registered retrospectively at the Pan African Clinical Trials Registry (PACTR) (Trial #: PACTR202301506140749 Date of Approval: 06/01/2023). Link: https://pactr.samrc.ac.za/Search.aspx

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Introduction

In 1912, coronary artery disease (CAD) was first described as an entity in the left main coronary artery (LMCA) lesions. It is well-known to be a single poor prognostic factor for post-intervention complications and death at various CAD stages.[1]

Its current prevalence is estimated to be 16-24%. For more than 30 years, revascularisation has been the gold standard therapy for symptomatic severe left main coronary artery disease (LM-CAD).[2]

Coronary artery bypass grafting (CABG) is still the most common type of cardiac surgery performed. On-pump and off-pump are the two most common CABG types. Off-pump CABG, unlike on-pump, is a newer method that does not require the use of a cardiopulmonary bypass machine.[3]

The most typical method of doing bypass surgery is on-pump CABG, but the procedure's inflammatory side-effects cause renal dysfunction, gastrointestinal (GI) irritation, and cardiac problems, forcing the surgeons to seek alternatives.[4]

According to a thorough literature review, on-pump CABG results in better revascularisation than off-pump CABG, whereas off-pump CABG has significantly reduced post-operative morbidity and mortality, especially in the elderly.[5]

Because of the haemodynamic changes that occur with altering the location of the heart during the grafting procedure, left main stem (LMS) disease was formerly regarded as a relative contraindication for off-pump CABG, but growing research has shown that this approach is a safe alternative to on-pump CABG.[6]

Off-pump rates fell after 2008 across both high-volume and intermediate-volume hospitals, and this approach is now used in fewer than 20% patients undergoing surgical coronary revascularisation in the United States.[7]

This decrease is likely related not only to the procedure's technical complexity and steep learning curve, but also, and perhaps more importantly, to the procedure's

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decreased long-term patency, increased rate of incomplete revascularisation, and lower long-term survival rates.[8]

The major justification for off-pump CABG is to avoid the negative consequences of on-pump CABG due to the systemic inflammatory mediators generated by blood components coming into touch with the bypass circuit's surface. Postoperative coagulopathy, neurological complications, thromboembolic complications, and organ dysfunction were all associated with on-pump CABG.[9]

The current study was planned to compare the outcome of off-pump and on-pump CABG in LM-CAD patients.

Patients and Methods

The randomised, controlled, prospective, multicentric study was conducted in 2020 during the period from January 2020 to December 2020 at Kafrelsheikh University Hospital (KUH), International Cardiac Centre (ICC) and Alexandria New Medical Centre (ANMC), Egypt. After approval from the ethics review committees of all the three institutions, the sample was raised using convenience sampling technique. Those included were LM-CAD patients of either gender who had preserved left ventricle (LV) function and sinus rhythm. Those excluded were patients having previous chest radiotherapy, previous cardiac surgery, chronic kidney disease (CKD), re-exploration for bleeding and combined cardiac surgery.

After taking informed consent from all the patients, they were randomised to on-pump surgery group I and off-pump surgery group II. The experimental (interventional group) was the off pump group. The control group for comparison was the Active treatment group or the on pump group.

For randomization the allocation sequence was generated using permuted block randomization technique and with a variable block size.[10] Allocation sequence/code was concealed from the person allocating the participants to the intervention arms using sealed opaque envelopes.[10]

Preoperative evaluation for all the patients was done, including complete clinical assessment, laboratory assessment using complete blood count (CBC), liver function test (LFT), renal function test (RFT), coagulation profile and arterial blood gas (ABG). Electrocardiogram (ECG), chest X-ray (CXR), echocardiogram and diagnostic coronary angiography.

The surgery was done under general anaesthesia (GA), and invasive arterial and central lines were inserted. Urinary catheter was inserted for urine output monitoring. Transoesophageal echocardiography (TEE) was used in all cases.

In group I, skin was disinfected, and midline sternotomy was done. Mammary retractor was used for left internal mammary artery (LIMA) harvesting. At the same time, the great saphenous vein was harvested from one or both legs.

Cardioplegia cannula was inserted in the most convex part of ascending aorta, followed by institution of cardiopulmonary bypass after activated clotting time reached >450 seconds. Inspection of the target vessels was done and marked via No. 15 blade.

Aortic clamp was used and cold cardioplegia was delivered into aortic root, followed by aortic root venting. After finishing the distal targets, the aortic clamp was removed and the length of the venous conduits was measured. Proximal anastomoses was done to the ascending aorta, followed by incising the pericardium to allow free course for LIMA to avoid tension by the lung.

The anaesthetist was asked to start ventilation of the lung, and the patient started coming off bypass after stabilisation of the heart rhythm, ABGs and reperfusion time.

Graft flowmeter was routinely used to assess the graft flow and the pulsatility index to assess the quality of the conduit. Protamine infusion was then started, and after half-a-dose of protamine, aortic and venous decannulation was done. Haemostasis of all surgical sites was done and closure of sternotomy in layers after inserting left pleural and retrosternal drains followed.

With respect to group II, the surgeons were experienced enough to employ off-pump technique.

Before starting anastomosis, haemodynamics were stabilised. Before LIMA to left anterior descending artery (LAD) anastomosis, the anaesthetist was asked to monitor the blood pressure (BP) so that if there was sudden hypotension when starting manipulating the heart, this could be solved by giving vasopressors.

The operating table was in Trendelenburg position to maintain the haemodynamics and to decrease the need for volume transfusion. It was very important to use different techniques to avoid hypothermia, and maintain normal body temperature because the heart lung machine was not in use.

After finishing LIMA harvesting, the sternal retractor was used to open the divided sternum. Several pericardial stay sutures using silk were used to allow best exposure of the target vessels. Unlike the on-pump technique, the stay sutures were not used in the right side of the pericardium to avoid compression of the right side of the heart.

A deep stitch was taken into the bottom of the pericardium

at the point between the left inferior pulmonary vein and the inferior vena cava.

Then special devices were used to stabilise the heart in the best position for each distal anastomosis. This was done using the octopus heart stabiliser and starfish heart stabilizer.

Using a rubbery silastic suture, the coronary artery was occluded proximal to the site of anastomosis. Also, arterial coronary shunts were available in different sizes according to the diameter of the coronary. A mister blower was used for carbon dioxide (CO2) blowing to assist visualising every bite.

The LIMA to LAD anastomosis was preferred to be the first graft to assure the reperfusion of the LAD territory and facilitate the haemodynamic stability during the next anastomoses. After finishing the distal anastomoses, the proximal anastomoses were done by partial clamping of the aorta, like the on-pump technique.

After finishing all the proximal anastomoses, the lie of all grafts was checked for twisting and determining the length. By using graft flowmeter, the graft flow was measured and pulsatility index was used to ensure the best quality of the grafts. The anaesthetist was asked to start infusion of protamine to reverse the action of the heparin given at the start.

Haemostasis was done for all the surgical fields and for closing the sternum in layers via stainless steel wire after the insertion of retrosternal and left pleural drains.

The patient was transferred to the intensive care unit (ICU), checked for haemodynamics, bleeding, inotropic support, and, after stabilising all the parameters, the process to disconnect the patient from mechanical ventilation was started.

All patients were assessed postoperatively for myocardial infarction (MI), acute kidney injury (AKI), pneumonia, sternal dehiscence and 3-month mortality.

Data was analysed using SPSS 20. Data was expressed as mean ± standard deviation, and as frequencies and percentages, as appropriate. Comparison was done between the groups using Mann-Whitney U test. Qualitative variables were tested using chi-square test. P<0.05 was considered statistically significant.

Results

Of the 60 patients, 44(73.3%) were men and 16(26.6%) were women. The overall mean age was 66.4±9.2 years. There were 30(50%) patients in each of the two groups.

Table: Intergroup comparison of postoperative complications.

Postoperative complications	On-pump (n = 30) n (%)	Off-pump (n = 30) n (%)	χ2	FEp
Myocardial infarction	2 (6.7)	1 (3.3)	0.351	1.000
Acute kidney injury	1 (3.3)	0 (0.0)	1.017	1.000
Pneumonia	3 (10.0)	1 (3.3)	1.071	0.612
Sternal dehiscence	1 (3.3)	0 (0.0)	1.017	1.000
Mortality in 3 months	2 (6.7)	1 (3.3)	0.351	1.000

There were 2(6.7%) cases of myocardial infarction in group I and 1(3.3%) in group II. There was 1(3.3%) case of acute kidney injury in group I and none in group II. There were 3(10%) cases of pneumonia in group1 compared to 1(3.3%) in group II. There was 1(3.3%) case of sternal dehiscence in group I and none in group II. Mortality at 3 months was 2(6.7%) in group I and 1(3.3%) in group II. There was no significant difference with respect to outcome between the groups (p>0.05) (Table).

Discussion

The current study found that LM-CAD patients treated by on-pump CABG had slightly higher rate of postoperative complications in the shape of MI, AKI, pneumonia, sternal dehiscence and 3-month mortality compared to the off-pump group.

In contrast, Benedetto et al. found that 3-year mortality was higher in the off-pump group compared to on-pump patients. This was due to the decreased rate of revascularisation in off-pump procedure for inferolateral wall arteries.[11]

In the current study, the surgeons had a high volume of off-pump surgeries, over 50 cases per year. It was initially thought on the basis of literature that complete revascularization was dependent solely on the experience of the surgeon to employ the off-pump technique.[12]

Similar to the current study, a multicentric randomised trial on 320 patients found that off-pump CABG was not inferior to on-pump CABG in terms of 3-month post-operative graft patency.[13]

A study reported that off-pump CABG had a beneficial effect in terms of AKI.[14]

The current study found 1 case of AKI in the on-pump group and no cases of AKI in the off-pump group, but this was not significantly different.

A study in 2005, comparing the pulmonary outcomes in off-pump versus on-pump CABG, found that no significant difference between the two techniques regarding the incidence of post-operative pneumonia.[15]

The current study found that the incidence rate of pneumonia in the off-pump group was 3.3% while in the on-pump group it was 10%. However, the difference was not significant.

Study reported that the incidence of sternal dehiscence in the on-pump group was higher due to mediastinitis compared to the off-pump group.[14,16] Similar results were found in the current study.

The current study has limitations as the sample size was not calculated which could have affected the power of the study. Besides, the sample was raised using convenience sampling technique, and the sample was not large enough as the study had a problem with the cost of surgical supplies despite having a qualified surgical team.

Conclusion

Off-pump CABG was found to be efficient and non-inferior to on-pump CABG in LM-CAD patients.

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Conflict of Interest: None.

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