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Original Article

Early Outcome of on Pump Beating Heart CABG Surgery

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Key Words : *Ischaemic heart disease, Cardiopulmonary bypass.*

Abstract:

Background: *Current cardioplegic technique during conventional coronary artery bypass grafting (CABG) does not consistently avoid myocardial ischemic damage in high risk patients. Alternatively revascularization without CPB is not always technically feasible. The on-pump beating technique eliminates global myocardial ischemia and thus reduce the mortality and morbidity in high risk patients. This study evaluates the early surgical outcomes of on-pump beating-heart CABG in comparison to conventional CABG.*

Methods: *In this prospective study 60 high risk patients with EURO-SCORE of 6 and above were prospectively allocated into two groups in non-randomized way. Among them 30 patients underwent on-pump beating-heart CABG and 30 patients underwent conventional CABG. The early surgical clinical outcomes were compared between the groups.*

Results: *On-pump beating heart CABG significantly reduced the duration of operation time, cardiopulmonary bypass time, postoperative ventilation time and intensive care unit (ICU) stay. Total blood loss and transfusion requirement were less with reduced Peak Creatine-Kinase level in On-pump beating heart CABG. 30 day mortality was less in On-pump beating heart CABG group (6.7% versus 13.3%). No significant differences between the groups were found in morbidity regarding stroke, renal failure, mediastinitis and atrial arrhythmia.*

Conclusion: *On-pump beating heart CABG can be performed safely in high risk patients. It is still associated with the detrimental effect of CPB but eliminates intra-operative global myocardial ischemia.*

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Introduction:

Coronary artery bypass grafting has become the standard operative treatment of ischemic heart disease. Cardioplegic arrest and the use of cardiopulmonary bypass (CPB) have led to tremendous progress in coronary artery bypass graft surgery.[1] As a result of improvement in invasive cardiology, most patients referred for CABG has diffused disease and poor ventricles. The global ischemia caused by conventional CABG could be detrimental in them. The OPCAB technique was developed with specific purpose of reducing mortality and the morbidity in high risk patients.[2] Many studies have shown the superiority of OPCAB in early & mid-term outcome compared with Conventional CABG.[3]

Unfortunately, during the extensive surgical manipulation and heart displacement necessary to perform multiple distal anastomoses, the OPCAB technique can cause episodes of haemodynamic instability that could lead to critical low coronary artery diastolic perfusion followed by severe

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complication and or death. Emergency conversion to Conventional CABG is a serious risk factor for operative mortality. These patients had a significantly higher episodes of postoperative cardiac arrest, multi-organ failure, vascular complications, peri-operative myocardial infarction and death.[4]

The on-pump beating heart CABG represents a merge of standard on-pump surgery and OPCAB technique. The main features of On-pump beating CABG are the use of CPB, the avoidance of cardioplegia and use of devices for OPCAB. This technique allows anastomosis on a beating heart while the pump provides systemic flow. The systemic temperature was kept normothermic, the CPB flow maintained at 2.5 L/min/m and perfusion pressure maintained at 70- 80mm Hg. On-pump beating CABG is particularly effective in protecting myocardial function in patients with severe left ventricular dysfunction. This technique enables complete revascularization in the patients of enlarged left ventricular size and impaired left ventricular function.[5]

Another very challenging subset of patients requiring revascularization includes those who have end stage coronary artery disease. They are not suitable for Conventional CABG due to poor LV function and they have suboptimal revascularization by OPCAB due to technical difficulties. In this subset the early & mid-term survival, morbidity and improvement of LV function shows clear benefit from on-pump beating CABG.[6]

An important element of the preoperative preparation for cardiac surgery is an assessment of the patient's surgical risk. Risk stratification allows patients insight into the real risk of complication & mortality. Various risk score systems have been developed to predict mortality as operative mortality is widely used as an indicator of the quality of cardiac surgery. The additive Euro-score model is a simple gold standard for risk assessment. It is now well established & has been validated across the world. It gives a quite useful estimate of risk in individual patient.[7] Using additive model, risks are calculated by adding relevant weight of any present risk factor to provide an estimate of predicted percent mortality. According to euro-score patient can be divided into different subgroups by additive risk prediction, Low risk: 0-2, Medium risk: 3-5, High risk: 6-13, very high risk: 14-24.

NICVD has been performing the central role in the field of cardiac surgery of Bangladesh. Conventional CABG surgery was introduced in 1985 & Beating heart CABG in 1997.On- pump beating heart CABG technique was introduced in NICVD in 2004 and more than 350 cases were performed till date. About 250 CABG cases are being performed in each year in NICVD involving all techniques. Due to change in disease pattern & improvement of PCI technology most of the CABG patients operated are of medium to high risk group. No previous work was undertaken to compare the on-pump beating heart CABG with Conventional CABG.

This study is undertaken to evaluate early surgical outcome of on-pump beating CABG in myocardial revascularization and to compare peri-operative outcome of on-pump beating CABG with Conventional CABG in terms of safety and efficacy.

Methods:

This study was conducted in the Department of Cardiac Surgery, National Institute of Cardiovascular Diseases, Bangladesh. Non-randomized controlled clinical study (Quasi experimental study) was conducted from January 2008 to December 2009. The study protocol was approved by the institutional review board. The study was carried out on 60 patients of coronary artery disease scheduled for coronary artery bypass graft surgery with high risk (score of 6 and above according to EURO- SCORE criteria). Patients with emergency CABG, redo CABG, combined CABG & valve or other congenital heart disease, cases where Cross-clamp will be applied during on-pump beating heart CABG.

So the sample size of this study was 60 which consist of 30 patients in each group. This was purposive and convenient sampling. The patients were divided into two groups on the basis of operative procedure: Group A: 30 patients with high risk (EURO- SCORE of 6 and above), who underwent on-pump beating heart CABG. (Experimental group). Group B: 30 patient with high risk (EURO- SCORE of 6 and above), who underwent conventional CABG (control group).

Per-operative variables were Operation time, Cardiopulmonary bypass time and number of bypass graft. Post-operative variables were Creatine Kinase (CK-MB) level, C-Reactive Protein (CRP) level, 30

days mortality, Ventilation time, blood loss, transfusion required, ICU stay, early operative complications stroke, renal dysfunction, arrhythmias, mediastinitis and re-operation.

All patients were followed up during the early postoperative period at discharge from hospital and up to 3 months after coronary artery bypass graft surgery. During the period patients were evaluated clinically by NYHA class, as well as by echocardiography for improvement of left ventricular function 3 months postoperatively after coronary artery bypass graft surgery.

Data were collected by use of interview schedule, investigation and from hospital records and was put in a pre-designed questionnaire. The numerical data obtained from the study were analyzed and significance of difference was estimated by using the statistical methods. Data were expressed in frequency, percentage, and mean plus minus standard deviation as applicable. Comparison between groups was done by Chi square test and Students' t test. All data were analyzed by using computer based Statistical Programs for Social Science (SPSS) program (version 11). p value less than 0.05 was considered as significant.

Results:

Regarding age determination 46% of subjects of Group-A, 60% of Group-B were between 55 – 65 years old. The mean age was almost identical between the groups (58.6 ± 7.8 vs. 60.0 ± 7.1; p = 0.357). The sex distribution of the patients between groups revealed that about 84% of patients in Group-A were male compared to 96.7% in Group-B. No significant difference was found between groups with respect to sex (p = 0.097). Comparison of body mass index between the study groups showed that All of the patients in Group-A were of normal weight compared to 90% in Group-B. No difference was found between groups in terms of BMI (p = 0.119). Risk factors demonstrate that over half (53.3%) of the patients in Group-A had diabetes mellitus, 80% hypertension, 20% hypercholesterolemia and 53.3% smoking habit compared to 63.3% had diabetes, 73.3% hypertension, 33.3% hypercholesterolemia and 90% smoking habit respectively in Group-B. Majority of the patients in Group-A (83.3%) and Group-B (90%) experienced recent (<3 months) myocardial infraction. No significant difference was found between the groups in terms of risk factors including diabetes, hypertension, hypercholesterolemia and myocardial infarction (p>0.05).

About 7% patients in Group-A had a history of arrhythmia compared to 3.3% in Group-B. Approximately 44% of patients in Group-A and 33.3% patients in Group-B presented with unstable angina. There was no significant difference between the groups in terms of history of arrhythmia and unstable angina (p = 0.500 and 0.426 respectively). Left ventricular ejection fraction was almost identical in the both groups (43.3 ± 4.3% vs. 43.8 ± 3.4%, p = 0.646). Summarization of the co-morbid conditions of the patients. Cerebrovascular disease and or carotid occlusion (> 50%) was found more than two times higher in Group-A (43.3%) than that in Group-B (20%). About 14% of patients in Group-A had peripheral vascular disease and 23.3% chronic obstructive pulmonary disease compared to 26.7% peripheral vascular disease and 40% chronic obstructive pulmonary disease in Group-B. Renal dysfunction was identically distributed in the both groups (10% vs. 6.7%, p = 0.500). Two (6.7%) patients in Group-A had preoperative NYHA class – II, 76.7% class – III and 16.7% class – IV, while 4(13.3%) in Group-B were classified as NYHA class-II, 23(76.7%) were class-III and 3(10%) class IV. The groups were almost identical in terms of NYHA functional class (p = 0.558). Based on CCS classification, 10% patients in Group-A fell into CCS class – II, 73.3% into class – III and 16.7% into class – IV, while in group B 13.3% of patients into CCS class – II, 73.3% into class-III and another 13.3% into class-IV The groups were homogeneous with respect to CCS class (p = 0.881) .Majorities of patients in Group-A (86.7%) and Group-B (83.3%) were presented with triple-vessel coronary artery disease. Nine (30%) of 30 patients in Group-A had left main stump disease, while 16.7% in Group-B had the same lesion. However, the groups were not statistically different with respect to diseased vessels (p = 0.058 and p = 0.222 respectively). Over 63% of Group-A and 70% of Group-B had Euro score 6. Thirty percent of patients in each group had Euro score 7. Euro score 8 was found only in 2(6.7%) cases of Group-A. The mean Euro score was almost identical between groups as evident by p = 0.354. Per-operative variables demonstrate that the operating time, cardiopulmonary bypass time and peak creatine kinase (CK-MB) were significantly lower in Group-A than those in Group-B (312.0 ± 26.3 vs. 396.5 ±

21.3 minutes, p < 0.001, 117.3 ± 13.7 vs. 173.2 ± 10.9 minutes, p<0.001 and 77.9 ± 30.7 vs. 128.7 ± 35.5 IU/L, p<0.001 respectively). The CRP was almost identical between groups (41.3 ± 4.8 vs. 40.8 ± 5.5 mg/L, p = 0.694). However, the number grafts required was higher in group-A than that in Group-B (3.4 ± 0.5 vs. 2.9 ± 0.3, p < 0.001) 30-day mortality was lower in group A than group B. (p = 0.335) Two (6.7%) of 30 patients in Group-A and 4(13.3%) patients in Group-B died within 30-days following coronary artery bypass graft surgery although P value is non-significant (p=0.335)

The early operative outcome like stroke, renal failure, atrial arrhythmia, mediastinitis were less in Group-A compared to those in Group-B (0% vs. 8.7%, p = 0.207; 3.7% vs. 13%, p = 0.246; 18.5% vs. 30.4%, p = 0.325 and 0% vs. 8.7%, p = 0.207 respectively). The ventilation time was much shorter in Group-A than that in Group-B (p = 0.012). Amount of blood loss and blood transfusion requires were considerably less in the former group than those in the latter group (p < 0.001). The mean stay in intensive care unit (ICU) was nearly 2 days less in the former group than that in the latter group (p < 0.001). The mean LVEF at discharge was identical in the both groups (p = 0.814)

Changes in LVEF following CABG. In both Group-A and Group-B LVEF improved significantly (43.2 ± 4.4 vs 51.6 ± 2.8) and (44.1 ± 3.5 vs 51.4 ± 2.9) from their baseline status (p < 0.001) before and after intervention. Data were analyzed using paired sample t-Test and were presented as mean ± SD.

The changes in NYHA functional class following CABG. NYHA class improved in both groups following surgery. But the improvement was not found to be statistically significant (p > 0.05).

In terms of postoperative NYHA class, about 90% of patients in Group-A fell into NYHA class-I and 10.7% class-II. In Group-B about 77% was class-I and the rest was class-II. There was no significant difference between the groups with respect to postoperative NYHA class (p = 0.197). χ^2 Test was employed to analyze the data; Fisher's Exact Test was done to analyze the data.

Table-I

Comparison of peroperative variables between two groups.

Peroperative variables	Group-A(n = 30)	Group-B(n = 30)	p-value
Operating time (minute)	312.0 ± 26.3	396.5 ± 21.3	<0.001
Cardiopulmonary bypass time (minute)	117.3 ± 13.7	173.2 ± 10.9	<0.001
Peak creatine kinase (IU/L)	77.9 ± 30.7	128.7 ± 35.5	<0.001
CRP (mg/L) 41.3 ± 4.8	40.8 ± 5.5	0.694	
Number of grafts required	3.4 ± 0.5	2.9 ± 0.3	<0.001

#Student's t-Test was employed to analyze the data and expressed as Mean ± SD.

Table-II

Comparison of postoperative outcome between two groups.

Postoperative outcome	Group-A(n = 28)	Group-B(n = 26)	p-value
Stroke* 00	2(8.7)	0.207	
Renal failure* 1(3.7)	3(13.0)	0.246	
Atrial arrhythmia#	5(18.5)	7(30.4)	0.325
Mediastinitis* 00	2(8.7)	0.207	
Ventilation time (hrs.)¶	7.4 ± 1.4	14.9 ± 2.7	0.012
Amount of blood loss (ml)¶	524.1 ± 135.3	935.2 ± 195.7	<0.001
Transfusion required (ml)¶	591.1 ± 210.9	913.0 ± 137.5	<0.001
ICU stay (days)¶	3.8 ± 0.5	5.4 ± 1.3	<0.001
LVEF (%) ¶ 51.6 ± 2.8	51.4 ± 2.9	0.814	

*Fisher's Exact Test was done to analyze data #Chi-square (?2) Test was employed to analyze the data.¶ Student's t-Test was done to analyze the data.

Discussion:

National Institute of Cardiovascular Disease, Dhaka, Bangladesh has been performing the central role in the field of cardiac surgery. NICVD is one of the best referral hospitals for CABG operation. The first CABG (on pump) surgery was performed at NICVD in 1985. OPCAB surgery was introduced in 1997 in NICVD[8] and subsequently in other cardiac centers of Bangladesh. On pump beating heart CABG was introduced in 2004, since then approximately 350 cases were performed. This was first study conducted to evaluate the early surgical outcome of on-pump beating heart coronary artery bypass graft surgery.

The mean age of the study was (58.6 ± 7.8) years for the on pump beating heart CABG and (60.0±7.1) years for on-pump arrested heart group (conventional CABG). Shinichi, et al.[1] reported a study of on-pump beating heart CABG showed mean age was (66.0±9.6) in on pump beating heart group and (66.7 ± 7.7) in conventional group, which was higher than our study.

Enricho, et al.[9] reported study of on-pump beating heart surgery for high risk patients showed the mean age was (69 ±7) years. Perrault, et al.[10] reported similar results. The mean age was 68 years for CABG patients.

All of the patients in Group-A were of normal weight compared to 90% in Group-B. No difference was found between groups in terms of BMI

All the patients were symptomatic with chest pain: most of the patients were in Canadian cardiology society (CCS) class III in both groups. Apart from pain all were symptomatic with exertional dyspnoea; most of them were of NYHA class III. Fouda, et al.[11] reported study of on pump beating CABG reveals 38.7% patients were in CCS grade III and 38.7% were in NYHA class III, which is below than our study because our study was conducted on high risk patients.

Our study subject revealed most the patients had co-morbidity., Cerebrovascular disease and more than >50% of Carotid occlusion were found two times higher in Group-A (43.3%) than that in Group-B (20%). 14 % had peripheral vascular disease, 23.3% with COPD and 10% with renal dysfunction. (Serum creatinine > 200 ìmol/L) in group A. while in group B, the percentage were 26.7% for PVD and 40% for COPD and 6.7% patients had renal dysfunction. Shinichi, et al.[1] reported study with 21.9% CVA, 12.3% PVD, 0.9%patients with COPD in on pump beating heart CABG group. Miyahara, et al.[12] published study of CABG, found preoperative incidence of COPD in 14%, stroke in 12%, and renal dysfunction in 11% patients.

In this study, most of the patients had history of recent myocardial infarction (MI within 90 days), Majority (83.3%) of the patients in Group-A and 90% in Group-B experienced recent myocardial infraction. About 7% patients in Group-A had a history of arrhythmia compared to 3.3% in Group-B. Approximately 44% of patients in Group-A and 33.3% patients in Group-B presented with unstable angina. There was no significance difference between groups in terms of history of arrhythmia and unstable angina.

Risk stratification of the study was done by Euro-Score. The pre-operative Euro score was 6 in 63.3% of patients in Group-A, 7 in 30% and 8 in 6.7%patients, compared to Euro-Score of 6 in 70%, and 7 in 30% of patients in Group-B. The mean Euro-Score for group A was (6.4±0.6) and (6.3±0.5) for group B. The Groups were identically distributed in terms of Euro score as evident by p = 0.354.

This was similar to study by Enricho, et al.[9] with preoperative EURO-SCORE was equal or above 8 in 73% patients of coronary artery bypass graft surgery. Fouda, et al.[11] reported similar result with EURO-SCORE value of 7 in patients underwent CABG.

Regarding operation related factor all the cases were performed as an elective case and other than isolated CABG cases were not included in the study to prevent disparity between the groups.

Result showed preoperative patient characteristics including coronary artery lesion and cardiopulmonary functional status were similar in the study groups. So these features have no influence on preoperative and postoperative clinical outcome.

Peroperative variables data showed the length of operation time was (312±26.3) min in group A and (396.5±21.3) min in group B. Cardiopulmonary bypass (CPB) time was (117.3±13.7) min in on-pump beating heart CABG and (173.2±10.9) min in conventional CABG group. All of the peroperative variable data showed result was statistically significant in favour of on pump beating heart CABG

($p < 0.001$). Shinichi, et al.[1] reported operation time was (306.6 ±69.9) min in on pump beating heart CABG and (345± 89.2) min in conventional CABG group.

Myocardial damage occurring due to the procedure was assessed by Peak Creatine kinase (CK-MB) level and inflammatory response by C- reactive protein (CRP) level. Peak Creatine kinase was higher in group B, CRP value was almost similar. Lower peak CK-MB level in on-pump beating heart CABG group ($p < 0.0007$) in comparison to conventional CABG, which was consistent with our result was reported by Shinichi, et al.[1].

Several postoperative variables have been compared between the groups in our study. Postoperative ventilation time was lower in case of on-pump beating heart CABG. One patient of conventional CABG group needed re-intubation due to respiratory complications and that patient needed prolonged ventilation of 56 hours.

Blood loss during post-operative period and requirement for blood transfusion were also less in group A in comparison to in group B. Intensive care unit (ICU) stay and ventilation time were significantly lower in group A. Shinichi, et al.[1] reported similar result with less ventilation time, shorter ICU stay, and lowered blood loss in patients underwent on pump beating heart CABG in comparison to conventional CABG.

Early postoperative outcome revealed higher postoperative morbidity in conventional CABG group. Incidence of atrial fibrillation was 18.5% in group A and 30.4% in group B. No patient developed stroke in group A in contrast to 2patients (8.7%) in group B with. 3.7 % of patient developed renal dysfunction in group A while that was 13% in group B. and 8.7% of group B patients developed mediastinitis in contrast to 0% in group A. The major postoperative morbidity was not statistically significant.

Shinichi, et al.[1] reported study showed stroke was observed in 2.6% cases in on pump beating heart CABG and 7.0% in conventional CABG. Postoperative transitory renal dysfunction developed in 2.6% patient in comparison to 5.3% in conventional CABG. Atrial fibrillation wasere observed in 25.4 % cases of on pump beating heart CABG and 7.9% in conventional CABG. All the features of early postoperative outcomes were consistent with our study.

No patient developed Perioperative myocardial infarction in our study which is similar to study by Enricho, et al.[9] Fouda, et al.[11] reported study of on pump beating CABG, that revealed 2.8% patient developed renal failure and 0.9% cases of respiratory complication and 2.8% patients of the study developed neurological dysfunction in the postoperative period.

30-day mortality after CABG was 2 (6.7 %) in on-pump beating heart CABG group and 4 (13.3 %) in conventional CABG. Shinichi, et al.[1] reported study of on-pump beating heart CABG with in hospital mortality of 2.6% in on-pump beating CABG and 9.6% in conventional CABG. In our study mortality was higher than that study, as they consider only in-hospital mortality.

Mortality of 3.8% in on-pump beating heart CABG which was lower than our study was reported by Fouda, et al.[11] Mortality rate was lower as the number of high-risk cases were less in that study.

Enricho, et al.[9] reported study of on-pump beating heart CABG for high risk patients required emergency CABG showed mortality of 8%, which was similar to our study. Perrault, et al.[10] reported mortality of 13.5% in high risk patients underwent on-pump beating heart CABG.

Predicted mortality according to standard Euro-Score model by risk groups showed, in high risk patients (Euro-Score ≥ 6) was 7.83%. Our study result of mortality was slightly lower than the predicted mortality showed the safety profile of on-pump beating heart CABG.

During postoperative follow-up evaluation of survivors, significant improvement of NYHA class was observed in both groups. By 3rd month after CABG. In terms of early post-operative (3rd month after CABG) NYHA class, 90% of patients of Group-A was NYHA class-I in relation to none before operation and 10% were class-II than those of group B, where 76.9% were in class-I in comparison to none preoperatively and 23.1% in class-II.

There was no significant difference between the groups with respect to postoperative NYHA class. But most of patients showed improvement NYHA functional class by two class in postoperative period but the

improvement was not statistically significant in case of group B. The improvement was not found to be significant, as it was assed only 3 months after CABG.

NYHA class was (1.5±0.8) in on-pump beating heart CABG group and (1.5±1.0) in conventional CABG group with p value of 0.6569 in study reported by Shinichi, et al.[1]

Left ventricular ejection fraction (LVEF) 3 months after CABG was (51.6 ± 2.8) in on-pump beating heart CABG patients and (51.4 ± 2.9) in case of conventional CABG patients. Improvement of left ventricular ejection fraction (LVEF) in the postoperative period in comparison to preoperative left ventricular ejection fraction was statistically significant in both groups. (p value < 0.001) Postoperative LVEF was almost identical in both groups with no significant difference. (p= 0.814)

Shinichi, et al.[1]reported left ventricular ejection fraction (LVEF) at discharge from hospital was (54.2±13.5) % in in on-pump beating heart CABG patients while it was (61.1±16.6) % in conventional CABG patients indicating incomplete revascularization as most of the cases of the study were of emergency nature.

Conclusion:

On-pump beating heart Coronary artery bypass graft surgery is safer than conventional Coronary artery bypass graft surgery in high risk patients. We recommended that On-pump beating heart Coronary artery bypass graft surgery may be considered safe in high risk patients. A prospective randomized trial and longtime follow-up are recommended to confirm our findings.

Study limitations:

Study sample size was small. Clinical outcomes were restricted only to 30 day mortality. There were no data beyond three months follow-up were available. Nothing is mentioned regarding quality of life after coronary artery bypass graft surgery. Other factors such as variation in surgeon's skill, echocardiography values, although unavoidable should also be considered.

Conflict of Interest - None.

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