ON-PUMP VERSUS OFF-PUMP MYOCARDIAL REVASCULARIZATION IN LOW RISK PATIENTS WITH MULTIVESSEL DISEASE – COMPARATIVE STUDY

Thesis

Submitted for the Complete Fulfillment of the Requirements of M.D Degree in

Cardiothoracic Surgery

By

Yasser Ahmed Boriek Ibraheem
(M.B., B.Ch; M.Sc. General Surgery)

Under the Supervision of

Prof. DR. Mahmoud Ahmed El-Batawi
Professor of Cardiothoracic Surgery,
Faculty of Medicine, Cairo University

Prof. DR. Amr Bastawisy Ahmed
Professor of Cardiothoracic Surgery,
Faculty of Medicine, Cairo University

Prof. DR. Hassan Mahmoud El-Sisi
ASS. Professor of Cardiothoracic Surgery,
Faculty of Medicine, Cairo University

Faculty of Medicine
Cairo University
2010

بسم الله الرحمن
الرحيم

ACKNOWLEDGMENT

“Above all, my deep thanks are to Allah,

the most kind and most merciful.”

I would like to express my profound gratitude and cardinal appreciation to the eminent Prof. Dr**. Mahmoud El-Batawi**, Professor of cardiothoracic surgery, Faculty of medicine , Cairo university , for his moral support, valuable supervision and constant encouragement. Prof. **El-Batawi** was not only mentor but also the father who provided me with support that sustained me through hard times and gave me the hope to face many challenges.

I would like also to express my deepest gratitude to my Prof. Dr. **Amr Bastawisy**, Professor of Cardiothoracic Surgery, Faculty of Medicine, Cairo University, for his concrete, continuous supervision and effective advice.

I would like also to express my deep appreciation to Prof. Dr **Hassan El-Sisi,** ASS**.** Professor of Cardiothoracic Surgery, Faculty of Medicine, Cairo University for his meticulous guidance and patient supervision.

Thanks are also to U. 24. My friends and colleagues they always supported me, sharing with me good and bad times.

I’m so grateful to my parents and my wife for their continuous encouragement and support.

Yasser Boriek

Jan, 2010

ABSTRACT

Background and Objectives: The performance of coronary bypass surgery without cardiopulmonary bypass ("off pump") may reduce perioperative morbidity and costs, but it is uncertain whether the outcome is similar to that involving the use of cardiopulmonary bypass ("on pump"). In fact, the advantage of using off-pump myocardial revascularization is being documented in high risk subgroups. Specific analysis performed in chronic pulmonary patients, elderly, and severe left ventricular dysfunction have demonstrated the advantage of using off-pump over on-pump myocardial revascularization. In light of these facts, our study is to compare on-pump versus off-pump myocardial revascularization in a specific population of low-risk patients and similar coronary artery disease. In this study on special subset of low risk patients, is off-pump procedure superior over conventional coronary artery surgery or not?

Methods and Results: In a single-center randomized trial, 50 low-risk patients with multivessel disease requiring CABG surgery at a single institution were prospectively randomized to have the procedure performed with CPB (n_25) or on the beating heart (n_25). Exclusion criteria for the trial included emergency procedure, concomitant major cardiac procedures, poor ejection fraction or LVEF<30%, and reoperation. The mean number of grafts performed per patient (mean ± SD 3.5 ± 0.9 for the on-pump group and 3.2 ± 0.9 for the off-pump group) with no statistically significant difference between both groups (P value>0.05). No mortality was detected in both patient groups. Patients in the cardiopulmonary bypass group required significantly more blood transfusions (1.6 ± 1.1 units vs. 1.0 ± 0.8 units, P<0.05). There were no significant differences between the CPB group and the beating-heart group in perioperative myocardial infarction (4% on-pump versus 4% off-pump), permanent stroke (4% versus 0%; *P*>0.05), new atrial fibrillation (8% versus 4%; *P*>0.05), and superficial sternal wound infection (4% versus 4%). There were significant differences between the CPB group and the beating-heart group in The mean time to extubation (9.4 hours on-pump vs. 6 hours off-pump, P<0.05), the mean stay in the intensive care unit (44.6 hours on-pump vs. 37.4 hours off-pump, P<0.05), and the median length of hospitalization (11.3 days on-pump vs. 9.2 days off-pump, P<0.05).

Conclusions: In low-risk patients, our findings suggest that excellent results can be obtained with both surgical approaches. The postoperative complications of both groups showed no statistically significant difference between the two groups. Ultimately, whether a patient benefits more from standard on-pump CABG or OPCAB may depend more on the familiarity, comfort, and skill of the individual surgeon with either procedure than on an intrinsic benefit.

Key words:

- EuroSCORE.
- Low Risk Patients.
- Off-Pump CABG.
- On-pump CABG.

CONTENTS

LIST OF TABLES

LIST OF FIGURES

List of Abbreviations

ACC	**A**merican **C**ollege of **C**ardiology
AHA	**A**merican **H**eart **A**ssociation
CABG	**C**oronary **A**rtery **B**ypass **G**rafting
CABG on-pump	**C**oronary **A**rtery **B**ypass **G**rafting on **C**ardiopulmonary **B**ypass
CAD	**C**oronary **A**rtery **D**isease
CHF	**C**ongestive **H**eart **F**ailure
COPD	**C**hronic **O**bstructive **P**ulmonary **D**isease
CPB	**C**ardio**P**ulmonary **B**ypass
CVA	**C**erebro**V**ascular **A**ccident
EF	**E**jection **F**raction
EuroSCORE	**E**uropean **S**ystem for **C**ardiac **O**perative **R**isk **E**valuation
HTN	**H**yper**T**e**N**sion
IABP	**I**ntra-**A**ortic **B**alloon **P**ump
IDDM	**I**nsulin-**D**ependent **D**iabetes **M**ellitus
ITA	**I**nternal **T**horacic **A**rtery
LAD	**L**eft **A**nterior **D**escending
LIMA	**L**eft **I**nternal **M**ammary **A**rtery
LITA	**L**eft **I**nternal **T**horacic **A**rtery
LVEF	**L**eft **V**entricular **E**jection **F**raction
NIDDM	**N**on-**I**nsulin-**D**ependent **D**iabetes **M**ellitus
OPCAB	**C**oronary **A**rtery **B**ypass **G**rafting on **C**ardiopulmonary **B**ypass
OPCAB	**O**ff-**P**ump **C**oronary **A**rtery **B**ypass
PCI	**P**ercutaneous **T**ransluminal **C**oronary **A**ngioplasty
PCIs	**P**ercutaneous **C**oronary **I**nterventions
PTCA	**P**ercutaneous **T**ransluminal **C**oronary **A**ngioplasty
PVD/CVD	**P**eripheral **V**ascular **D**isease/**C**ardio**V**ascular **D**isease
RCA	**R**ight **C**oronary **A**rtery
RIMA	**R**ight **I**nternal **M**ammary **A**rtery
RITA	**R**ight **I**nternal **T**horacic **A**rtery
TEE	**T**rans**E**sophageal **E**chocardiography
ULN	**U**pper **L**imit of **N**ormal

Rationale and Background

Off-pump myocardial revascularization is considered a new alternative to perform coronary artery with minimal damage.

Several studies have been done to identify clinical differences between off-pup versus on-pump myocardial revascularization**, (Gerola, et al., 2004).**

In a retrospective study comparing patients with multivessel disease operated on on-pump and off-pump, no difference in morbidity and mortality, was found, however, there was a lower necessity of blood transfusion in patients operated on off-pump**, (Kshettry, et al., 2000).**

In a prospective not randomized, study no difference between the two groups in the incidence of either postoperative morbidity or in the use of blood was found. Standing out is that all patients were multivessel in both groups, and the number of the grafts in the patients operated on off-pump was significantly lower**, (Bull, et al., 2001).**

On the other hand, in a prospective and randomized study excluding patients with lesion in the distal portion of the circumflex artery, show the number of grafts per patient was similar. No difference in hospital mortality was found, but in the off-pump group there were lower pulmonary infections, necessity of vasoactive drugs, bleeding, blood transfusion, minor intubation time, in-stay ICU, and lesser cost, **(Ascione, et al., 1999).**

Significant difference was found in in-hospital morbidity in the off-pump group, with less of blood products and inotropic drugs, minor incidence of atrial fibrillation, chest infection, time to extubation, and less, intensive care unit and hospital stay. In fact, this study in randomized studies was one of the few studies that found a significant difference in low risk-patients regarding main hospital morbidities, and not only a difference in the use of blood products and hospital stay**, (Angelini, et al., 2002).**

Several times the off-pump approach was performed in patients with lesion in one or two vessel disease, whereas cardiopulmonary bypass was used in patients with multivessel disease. In addition, in

some prospective studies in patients with multivessel disease, the group operated on off-pump received a significantly lower number of grafts when compared with patients operated on-pump**, (Czerny, et al., 2001)(van Dijk, et al., 2001).**

In light of these facts, our study is to compare on-pump versus off-pump myocardial revascularization in a specific population of low-risk patients and similar coronary artery disease.

Hypothesis

Heterogenous results in the literature were presented. In some reports is shown superiority in the off-pump procedure over conventional surgery, in others there is shown no difference between the methods**, (Gerola, et al., 2004).**

In fact, the advantage of using off-pump myocardial revascularization is being documented in high risk subgroups**, (Yokoyama, et al., 2000)**. Specific analysis performed in chronic pulmonary patients **(Guller, et al., 2001),** elderly **(Bull, et al., 2001),** and severe left ventricular dysfunction **(Arom, et al., 2000),** have demonstrated the advantage of using off-pump over on-pump myocardial revascularization**, (Gerola, et al., 2004).**

Several of the comparative studies, including multivessel diseases, have described a number of grafts per patients significantly lower in patients operated on off-pump, **(kshettry, et al., 2000) (Bull, et al., 2001)**. This represents a bias of selection in retrospective analysis, **(Gerola, et al., 2004)**. In our study, we eliminated the possible bias making the same number of grafts per patient.

In this study on special subset of low risk patients with multivessel disease, is off-pump procedure superior over conventional coronary artery surgery or not?

Objective

To evaluate hospital mortality and morbidity after myocardial revascularization, comparing on-pump versus off-pump in a special subset of low-risk patients with multivessel disease.

INTRODUCTION

Risk stratification plays an important role in cardiac surgical practice throughout the world. The selection of appropriate scoring systems for the evaluation of hospital performance and its improvement has become an important issue. The risk models provide an important tool to assess the clinical outcomes of cardiac surgery in an objective risk adjusted manner, and allow valid and realistic comparisons to be made between countries, regions, hospitals and even individual surgeons. Various scoring systems have been developed to predict early mortality and/or morbidity after adult heart surgery**, (Toumpoulis, et al., 2004).**

The EuroSCORE (European system for cardiac operative risk evaluation) is a scoring system for the prediction of early mortality in cardiac surgical patients on the basis of objective risk factors. EuroSCORE is a simple, objective and up-to-date system for assessing heart surgery, soundly based on one of the largest most complete and accurate databases in European cardiac surgical history. It is essential that the risk stratification system is objective and resistant to manipulation. This is achieved by the selection of real, measurable and easily available risk factors. In addition, it is important that as few risk factors as possible are determined by surgical decision-making. Most Euro- SCORE risk factors are derived from the clinical status of the patient. Only four risk factors are related to the operation and these are factors that are difficult to influence through subtle variation in surgical decision-making**, (Nashef, et al., 1999).**

It has been favorably received and widely used since it was first introduced in 1999, **(Michel, et al., 2003)** Based on a large and tightly controlled patient database, **(Roques, et al., 1999)** drawn from across Europe, the system used logistic regression methodology to identify and give appropriate weight to various risk factors related to mortality in adult heart operations. In order to simplify the use of the system and to encourage risk assessment even in the absence of information technology, EuroSCORE was published as an additive system in which each risk factor is given a “weight” or a number of points which, when added, provide an estimate of the percent predicted operative mortality for a patient

undergoing a particular procedure. The system has now been extensively tested and found to be valid throughout Europe, **(Kurki, et al., 2002),** in North America**, (Nashef, et al., 2002)** and in Japan, **(Kawachi, et al., 2002)** There is evidence of rapidly expanding use of EuroSCORE worldwide, **(Michel, et al., 2003).**

Those who provide and use health care recognize that the resources for such care are limited. It is now established that the cost of treatment must be taken into consideration in decisions about health care provision Future debate in this field will focus on the quality of treatment and the measurement of this quality. In cardiac surgery, it has long been accepted that operative or hospital mortality is an indicator of quality of care. This is true to a large extent: death following heart surgery is often due to failure to achieve a satisfactory cardiac outcome, itself the cause of major early morbidity as well as poor longterm results. Crude operative mortality fails as a measure of quality only when there are major variations in casemix. For operative mortality to remain a valid measure of quality of care, it must be related to the risk profile of the patients receiving surgery, hence the need for a reliable risk stratification model, already recognised by earlier workers in this field, **(Nashef, et al., 1999).**

There is another reason for the development and regular use of risk stratification in the assessment of cardiac surgical results. Doctors and hospitals operate in an increasingly open system where the availability of results and public accountability may influence decision-making. Without risk stratification, surgeons and hospitals treating high-risk patients will appear to have worse results than others. This may prejudice referral patterns, affect the allocation of resources and even discourage the treatment of high-risk patients. This is especially undesirable in cardiac surgery because it is precisely this group of patients which stands to gain most from surgical treatment, in spite of the increased risk**, (Mark, et al., 1996).** Risk stratification helps eliminate the bias against high-risk patients**, (Hannan, et al., 1997).**

An individual patient will either survive or die after cardiac surgery. Clearly, no scoring system will predict the specific outcome for every patient. Risk stratification, however, will inform patients