

**American University of Armenia  
School of Public Health**

**Clinical Outcomes and Quality of Life after Off-pump versus On-pump  
Coronary Artery Bypass Grafting in Armenia**

Master of Public Health Integrating Experience Project

Professional Publication Framework

By

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## Abbreviation list

<b>ACEi</b>	angiotensin-converting enzyme inhibitors
<b>ARB</b>	angiotensin receptor blockers
<b>ASA</b>	acetylsalicylic acid
<b>BMI</b>	body mass index
<b>BMS</b>	bare-metal stent
<b>CABG</b>	coronary artery bypass grafting
<b>CAD</b>	coronary artery disease
<b>CBP</b>	cardiopulmonary bypass
<b>CCB</b>	calcium channel blockers
<b>CVA</b>	cerebral-vascular accident
<b>COPD</b>	chronic obstructive pulmonary disease
<b>DES</b>	drug-eluting stent
<b>EuroSCORE</b>	European System for Cardiac Operative Risk Evaluation
<b>GI</b>	gastrointestinal disease
<b>ICU</b>	Intensive care unit
<b>LAD</b>	left anterior descending
<b>MACCE</b>	major adverse cardiac and cerebrovascular events
<b>MI</b>	myocardial infarction
<b>NMMC</b>	Nork Marash Medical Center
<b>NSTEMI</b>	non-ST elevation MI
<b>OM</b>	obtuse marginal
<b>OSIR</b>	organic systemic inflammatory response

<b>PCI</b>	percutaneous coronary intervention
<b>PDA</b>	posterior descending artery
<b>QoL</b>	quality of life
<b>STEMI</b>	ST elevation MI
<b>TIA</b>	transient ischemic attack
<b>VAS</b>	visual analogue scale

## **Abstract**

**Background:** Coronary artery disease (CAD) remains the leading cause of mortality and morbidity worldwide. Coronary artery bypass grafting (CABG) is one CAD treatment approach. It can be conducted with (on-pump) or without (off-pump) the use of a heart-lung machine. The long-term benefits of off-pump versus on-pump (traditional) CABG are debatable. This study compared on-pump and off-pump 5-year event free survival from major cardiac and cerebrovascular events (MACCE) and quality of life of patients who underwent CABG surgery.

**Methods:** A retrospective cohort design study was conducted. The study population included all patients who underwent CABG at Nork Marash Medical Center (NMMC), Armenia from 2009 to 2010. Data were collected from patient telephone surveys (March 2015), the NMMC electronic surgical database, and medical records.

**Results:** Among 528 patients, 407 (77.08%) underwent on-pump and 121 (22.92%) off-pump CABG. The groups differed at baseline by age, gender, prevalence of hypertension, cerebrovascular disease, gastrointestinal disease, and diabetes. The average EuroSCORE was significantly higher in the off-pump group, indicating a higher surgical risk. The mean follow-up time was 58.2 months for the on-pump and 59.5 months for the off-pump groups. Overall patient health status of patients, estimated via the EQ-5D visual analogue scale, showed no significant differences. After adjustment for EuroSCORE and diabetes, the hazard of developing MACCE was similar (HR=0.96 for on-pump versus off-pump, 95% CI: 0.56-1.65).

**Conclusion:** At 5-year follow-up, no significant differences were observed in the risk of developing major cardiac and cerebrovascular events or quality of life between the off-pump and on-pump CABG patients. Further research is needed to define the patient populations that will benefit the most from each type of surgery.

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## **1. Introduction**

### **1.1 Disease burden and significance**

Coronary artery disease (CAD) remains the leading cause of mortality and morbidity, representing an important public health issue.<sup>1</sup> In 2012, 7.4 million deaths or 13.2% of all deaths were attributed to CAD worldwide.<sup>2</sup> In the United States, where about 385,000 people die of CAD each year, the annual cost of CAD is about \$108.9 billion if considering only costs of productivity losses and medications.<sup>3</sup> Historically, CAD is considered as a “man’s disease”. According to the National Health and Nutrition Examination survey from 2007 to 2010, the prevalence of CAD is 21% in men and 11% in women of 60-79 years of age, and 35% in men and 19% in women 80 years and older<sup>4</sup>. However, it is the leading cause of deaths for women of all ages, with an annual mortality rate higher than that of breast cancer.<sup>5</sup> In general, women with CAD are older and have lower probability of CAD before menopause. Women’s CAD incidence rate lags about 10 years behind men’s.<sup>5</sup>

### **1.2 Clinical representation of CAD**

Clinical manifestation of CAD includes stable and unstable angina, cardiac death, acute myocardial infarction (MI) and acute coronary syndrome. Angina may be presented with symptoms such as dyspnea, nausea, weakness, sense of impending doom, apprehension, sweating and others.<sup>6,7</sup> Patients with MI may present with chest pain and characteristic ST elevation on the electrocardiogram, known as ST elevation MI (STEMI) or without ST elevation, known as non-ST elevation MI (NSTEMI).<sup>8</sup> STEMI is a clinical characteristic of myocardial ischemia with released myocardial necrosis biomarkers and persistent ECG ST elevation.<sup>9</sup> NSTEMI or unstable angina represents a clinical syndrome, usually caused by atherosclerotic

CAD and has an increased risk of MI and cardiac death. It is defined with ST depression or prominent T-wave inversion or with the absence of ST elevation in the presence of biomarkers of necrosis.<sup>10</sup>

### **1.3 CAD treatment**

Treatment strategies of CAD currently include medication management, invasive treatment such as percutaneous coronary intervention (PCI) with stents and surgical intervention known as coronary artery bypass grafting (CABG). According to the CDC 395,000 CABG procedures and 454,000 insertion of coronary artery stent were conducted in USA during 2010.<sup>11</sup> PCI/CABG ratio was 1.1 from 2001 to 2002, which increased to 2.7 in 2011 in Saudi Arabia.<sup>12</sup> In comparison, the ratio of PCI/CABG increased from 1.1 to 3.1 since 1998 in the UK.<sup>12</sup> The ratio of PCI/CABG increased from 1.19 to 8.04 from 1994 to 2008 respectively in USA.<sup>12</sup> Based on the results of 2 different studies conducted in Armenia, the ratio of PCI/CABG was 1/2.3 at NMMC in Armenia.<sup>13,14</sup>

Multiple medications in combinations are used to treat patients with CAD including antiplatelets (e.g., aspirin or acetylsalicylic acid (ASA), ticlopidine, clopidogrel), statins (e.g., atorvastatin, lovastatin, simvastatin), beta-blockers (e.g., bisoprolol, metoprolol), nitrates (e.g., nitroglycerin, mono- or dinitrate isosorbide), calcium channel antagonists (e.g., nifedipin, verapamil, diltiazem) and angiotensin II receptor antagonists (e.g., losartan, valsartan), and angiotensin-converting enzyme inhibitors (e.g., captopril, enalapril).<sup>15,16</sup>



Several types of PCI exist, including drug-eluting stents (DESs) and bare-metal stents (BMSs). The choice of the intervention type is based on many factors, such as left main disease, in-stent stenosis, small vessels, expected procedure requiring discontinuation of dual antiplatelet therapy, high risk of bleeding, diabetes and other factors.<sup>17</sup>

Coronary artery bypass grafting is a surgery on coronary arteries that can be conducted with the use of a heart-lung machine known as cardiopulmonary bypass (CPB), otherwise called on-pump CABG surgery and without the use of CPB, known as off-pump CABG surgery.<sup>18</sup> Specific indications for medical or invasive/surgical management for CAD exist.

Compared to medical therapy, CABG has lower incidence of postoperative myocardial infarction, lower incidence of cardiac death and lower rate of additional revascularization based on 10-year follow up study.<sup>19</sup> According to 2011 guidelines for the management of patients undergoing coronary artery revascularization, CABG should be favored over PCI, when the diameter of coronary artery stenosis is 50% or less in unprotected Left Anterior Descending (LAD) artery, presence of 3-vessel disease with or without proximal LAD artery disease or 2 vessel disease with proximal LAD artery disease, presence of diabetes mellitus in patients with multi-vessel disease and others.<sup>17</sup> Several studies conducted during the last two decades compared CABG with PCI and found that, compared to PCI, CABG is associated with improved angina symptoms<sup>17</sup> and lower repeat revascularization rates, which in its turn leads to increased survival rate.<sup>6</sup> However, both forms of interventions have their strengths and weaknesses, and should be used in a balanced way.<sup>6</sup>

#### **1.4 Outcomes after on-pump versus off-pump CABG**

CABG is still one of the most frequently conducted surgical procedures in the United States and is most frequently performed using cardiopulmonary bypass (pump) and cardioplegic arrest, to increase the safety of constructing anastomoses<sup>20</sup>. This approach is otherwise known as on-pump CABG.<sup>21,22</sup> The use of cardiopulmonary bypass has been identified as the main reason of inducing an organic systemic inflammatory response (OSIR) as a result of mechanical trauma to blood initiated by extracorporeal circuit.<sup>23</sup> OSIR has been associated with high risk of postoperative adverse events such as neurological, respiratory, gastrointestinal and renal dysfunctions, bleeding, hemolysis, and increased susceptibility to infections, ultimately increasing operative morbidity and overall recovery time.<sup>24,25</sup> As a solution to avoiding the risks of CPB, off-pump CABG was introduced into practice.<sup>20</sup>

Off-pump CABG was designed for those patients with high risk of complications of CPB.<sup>27</sup> Such patients can be elderly and those with comorbid conditions, as renal dysfunction, carotid disease, chronic pulmonary disease, atherosclerotic ascending aortic disease and peripheral vascular disease.<sup>28</sup> Further development tended to include also diabetics and those undergoing reoperative CABG surgery.<sup>29</sup> Hemodynamic instability, poor quality target vessels including intramyocardial vessels, diffusely diseased vessels and calcified coronary vessels are considered as absolute contraindications for off-pump CABG.<sup>27</sup> Other precautions as cardiomegaly/congestive heart failure, critical left main disease, small distal targets, recent or current acute MI, cardiogenic shock, poor left ventricular function (LVEF<35%) are considered as relative contraindications to off-pump CABG.<sup>27</sup>

Several large randomized clinical trials found no significant difference between on-pump and off-pump CABG in terms of mortality.<sup>20,29-31</sup> Cardiac outcomes, such as death, MI, stroke, and coronary revascularization also have the same probability of occurrence according to one multicenter, randomized clinical trial in low-risk patients' group<sup>20</sup>. In contrast, a recent observational study in Korea found higher risk of long-term mortality (median follow-up of 6.4 years) in patients undergoing off-pump CABG (HR: 1.43; 95% CI: 1.19 to 1.71).<sup>32</sup> Other studies report decreased morbidity, reduced length of hospitalization, cost effectiveness and decreased mortality in off-pump CABG group.<sup>23,33</sup> Off-pump CABG procedure also has lower prevalence of renal or respiratory failure and is a surgery of choice for diabetic patients regarding survival (early and mid-term) rate and postoperative complications.<sup>34,35</sup>

The results from recent meta-analysis studies comparing outcomes after on-pump and off-pump CABG are conflicting and need further investigation. The meta-analysis by Godinho et al compared outcomes of on-pump and off-pump CABG procedures in 9 randomized clinical trials from USA, Japan, Italy and Czech Republic.<sup>25</sup> Overall 75,086 patients were included in the meta-analysis, with variable patient inclusion and exclusion criteria such as age, size of stenosis and comorbidities. The study reported that compared to on-pump CABG, off-pump CABG resulted in 18% reduction in the risk of mortality and 27% reduction risk in the risk of postoperative cerebral-vascular accident (CVA) with no differences in the risk of developing kidney complications or septicemia.<sup>25</sup> The authors concluded that considering the fact that both techniques are still evolving and have indications and relative advantages and disadvantages for certain patient groups, more studies are needed to demonstrate the clinical superiority of off-pump CABG in specific clinical contexts.<sup>25</sup>

In contrast, another recent meta-analysis comparing on-pump and off-pump CABG procedures in 86 randomized clinical trials including 10,716 participants found differing results.<sup>37</sup> All-cause mortality was reported in 75 trials, including some at long-term follow-up. Analysis in 10 trials with low risk of bias showed 30% increased risk of all-cause mortality in off-pump CABG patients compared to on-pump. No significant differences were found regarding MI, coronary re-intervention, and renal insufficiency. Though stroke occurred in 84/4,527 patients in on-pump group and 60/4,527 in the off-pump group reporting no significant differences among the groups, the analysis using the fixed-effect model showed significantly higher risk in on-pump group. The meta-analysis also showed reduced risk of atrial fibrillation after the intervention for off-pump CABG group.<sup>37</sup>

A study was conducted in Denmark evaluating on-pump versus off-pump CABG procedure among 341 participants with a median 3.7 years of follow-up. Major outcome of the study was MACCE, including all-cause mortality, cardiac arrest with successful resuscitation, stroke, coronary re-intervention, acute MI and cardiogenic shock. No significant differences were found in the outcome of MACCE among on-pump and off-pump groups, besides all-cause mortality that was higher in the off-pump group.<sup>38</sup>

The meta-analysis by Takagi et al compared the development of MACCE between the on-pump and off-pump CABG patients in 8 large randomized clinical trials (n>100 in each study) that followed patients for more than 1 year.<sup>39</sup> Overall, the meta-analysis included 10,954 patients and showed no significant difference in MACCE. The definition of MACCE, however, was variable

across the studies that used some composite of mortality, MI, stroke, repeat revascularization, cardiac readmission, renal failure, recurrent angina, and cardiogenic shock.<sup>39</sup>

In a meta-analysis of 5 randomized trials and 17 observational studies including a total number of 104,306 participants, reported statistically significant 7% increased risk of all-cause mortality among off-pump CABG group compared to on-pump CABG group in long-term (>5 years) follow-up.<sup>40</sup>

Based on the findings of the previously reported meta-analysis of 22 studies, it was suggested, that guidelines should be developed for off-pump CABG procedure, including criteria for surgeon training, institutional requirements, postoperative management, patient selection and standardization of operative techniques.<sup>41</sup> Concerns were raised that the decreased graft per patient index and increased need of early revascularization can lead to an increased risk of MACCE occurrence after off-pump CABG surgery. It was also established that registries should be used to monitor the short-term (30 days) and long-term (5-years) outcomes after off-pump CABG, including MACCE. Overall, it was concluded that more investigations should be conducted regarding MACCE after off-pump CABG procedure.<sup>41</sup>

### **Quality of life**

Studies showed that patients' quality of life (QOL) is improved after both on-pump and off-pump CABG. No significant difference was found at 3 months of follow-up between the groups of elderly patients with moderate to high-predicted preoperative risk beside the role limitation due to mental health and emotional problems (psychological well being), which was better in on-

pump CABG group.<sup>42,43</sup> The differences in cognitive function was insignificant.<sup>42,43</sup> A study compared QoL measured by SF-36 in 185 patients and reported no significant difference at 1-year follow-up after adjusting for baseline.<sup>44</sup> Another study found better results in emotional and physical aspects in patients after off-pump CABG procedure compared to on-pump CABG patients.<sup>44</sup>

### **1.5 Situation in Armenia**

The Armenia Health System Performance Assessment 2009 report identified cardiovascular disease (CVD) as the most prevalent cause of mortality, 54.9% and 49.9% in 2002 and 2008 respectively.<sup>45</sup> According to 2012 Coronary Heart Disease Statistics by the British Heart Foundation, in Armenia the age-standardized mortality rates of CAD in men and women changed from 389 to 407 and from 291 to 252 per 100,000 populations between 1985 and 2009 respectively.<sup>46</sup> According to the same source, CAD-specific age-standardized hospital discharge rate increased from 334 in 1980 to 505 per 100,000 in 2009.<sup>46</sup>

### **1.6 Rationale for the study**

Nork Marash Medical Center (NMMC) was established in 1993 and is Armenia's leading surgical center, providing outpatient and inpatient services for both Armenians and residents of other countries. NMMC has the highest volume of invasive cardiac procedures and surgeries as compared to the other centers in Armenia. As per discussion with NMMC specialists, more than 500 primary isolated CABG procedures are conducted in NMMC annually.<sup>47</sup> The prevalence of on-pump CABG procedure is much higher, than that of off-pump CABG. In 2003, 394 patients underwent isolated CABG procedure in NMMC where CPB was used in 63% of cases.<sup>13</sup> As per

discussion with NMMC surgeons, about 5-7 years ago, surgeons preferred off-pump CABG over on-pump almost in all the cases not having contraindications. Consequently, patients with sustainable clinical conditions were assigned to off-pump CABG. But nowadays the utilization of off-pump CABG procedure is lower as it is mostly used in patients with higher risk of comorbid conditions, as peripheral vascular disease, renal dysfunction, carotid disease, chronic pulmonary disease and atherosclerotic ascending aortic disease.<sup>26,27</sup> While ongoing debates are occurring about differences in outcomes between on-pump and off-pump CABG, no studies have investigated this issue in Armenian setting. The aim of the proposed study is to investigate whether off-pump CABG surgery improves clinical and patient-reported outcomes comparing to on-pump CABG surgery in Armenian patients.

### **1.7 Study research questions**

The primary research question of the study was:

Does the risk of developing major adverse cardiac and cerebrovascular events (MACCE) (including death, nonfatal MI, repeat revascularization, stroke) differ between on-pump and off-pump CABG after 5-year of follow-up?

The secondary (exploratory) research questions were:

1. Do on-pump CABG and off-pump CABG differ in terms of hospital complications, duration of surgical procedure, intensive care unit length of stay, and hospital length of stay?
2. Do the quality of life and health perception of patients differ after off-pump CABG compared to on-pump CABG group at 5-year of follow-up?

## **2. Methods**

### **2.1 Study design**

The study used a retrospective cohort design including all patients who underwent on-pump and off-pump CABG from 2009 to 2010 at NMMC.

### **2.2 Study population**

The target population was the group of patients, who underwent either on-pump or off-pump CABG procedure at NMMC. The study population was Armenian patients who met the following inclusion criteria:

- All the patients, who underwent CABG from January 1, 2009 to December 31, 2010 at NMMC
- Patients with available contact information
- Patients speaking Armenian
- Residents of Armenia
- Patients willing to participate

The exclusion criteria were the following:

- Patients who had CABG procedure in the past
- Patients with missing medical records

### **2.3 Sources of data**

The NMMC Surgical database was used as the sampling frame to define the list of patients who underwent CABG surgery during the defined study period and who were Armenian residents and



also had valid contact information. Primary data collection was conducted by telephone survey to assess 5-year outcomes after CABG procedure. During phone surveys patients were consented for access to their medical records. Afterward, information was extracted from the medical records and follow-up forms.

## **2.4 Study instruments**

Journal forms (Appendix 1) were used to obtain contact information of the patients from the electronic database for telephone interviews. Two types of instruments were developed. Firstly, an interviewer-administered questionnaire with two sections for telephone survey was developed, that was used to assess QoL of patients (1<sup>st</sup> section) and the risk of developing MACCE (2<sup>nd</sup> section) (Appendix 3). The EQ-5D-5L questionnaire, a previously validated and reliable generic questionnaire for assessing patients' QoL, was used.<sup>48</sup> Afterwards, the data extracted from surgical database and medical charts was collected in the Medical Data Abstraction Forms (Appendix 2).

## **2.5 Sample size calculation**

A census was conducted including all patients who had CABG from 2009 to 2010. Based on preliminary information, approximately 450-500 CABG procedures are conducted in NMMC per year, and the proportion of off-pump cases has been decreasing gradually since 2009 (e.g., approximately 26% of all CABG cases in 2009, and 12% in 2010). Overall, 942 Armenian patients underwent CABG from 2009 to 2010 at NMMC.

## **2.6 Statistical considerations**

The data collected from interviews and medical records were entered into SPSS 17 software package. Single data entry was performed with logical and range checks to assess the accuracy. Categorical data were summarized using frequencies and percentages, and continuous data were summarized using means and standard deviations. Independent t-test was used to compare continuous data and Fisher's exact test or Chi-square tests were used to compare categorical data. The Kaplan-Meier product-limit method was used to estimate the survival from MACCE for each group. Multivariable Cox proportional hazards regression analysis was used to compare survival rates between on-pump and off-pump CABG groups. The final model was developed first by selecting all variables with  $p < 0.25$  from the univariate analysis, and then using backward elimination by applying the log-likelihood ratio test. The proportional hazard assumption of the Cox model was tested for the final model.

### *Study variables*

The primary dependent variable was 5-year average survival rate from MACCE. The secondary dependent variables were hospital complications, intensive care unit length of stay, hospital length of stay and quality of life. MACCE was defined as the composite of death, nonfatal MI, repeat revascularization or stroke. Repeat revascularization was defined as a repeat CABG or PCI intervention. Hospital complications were defined as all the events occurring within the index hospitalization.

The independent variables were gender, age, preoperative arrhythmia, ejection fraction, stable angina, unstable angina, MI, MI onset time, heart failure, inotropic drug use after the surgery, clamp time, intubation period, ICU stay duration (hours), CBP duration, surgery duration, preoperative cardiogenic shock, current smoking status, BMI, hypercholesterolemia, hypertension, diabetes, GI disease, cerebrovascular disease (stroke/TIA), creatinine level ( $\mu\text{mol/L}$ ), extracardiac arteriopathy, neurological dysfunction, chronic lung disease (COPD), active endocarditis, critical preoperative state, surgery on thoracic aorta, other than isolated CABG, previous PCI, previous cardiac surgery, number of diseased vessels, type of the diseased vessels, number of grafts conducted, in hospital complications, medication at discharge, EuroSCORE I (European System for Cardiac Operative Risk Evaluation) .

EuroSCORE is scoring system widely used in clinical research to predict operative mortality after cardiac surgery and for risk-adjustment.<sup>5,50</sup> EuroSCORE I was originally developed in 1999 and included 17 variables. EuroSCORE II is the new, updated version of the score. The study by Biancari et al in patients undergoing CABG showed better results for EuroSCORE II compared to the original logistic EuroSCORE I in predicting morbidity and operative mortality after CABG.<sup>49</sup> EuroSCORE II is a better predictor for late postoperative survival for patients undergoing CABG procedure.<sup>49</sup> Unfortunately, because of limited availability of the additional predictors needed for EuroSCORE II, the original EuroSCORE I was used for the study.

## **2.7 Ethical considerations**

The study protocol was reviewed by the Institutional Review Board (IRB)/Committee on Human Research of the American University of Armenia. The student investigator called patients to obtain their oral consent to participate in the survey and access their medical records.

## **3. RESULTS**

### **3.1 Administrative data**

Of the 942 patients, 401 were not reachable (no response to the call, patient out of the country, wrong number, phone number not provided, etc.). Of the 541 patient households that were contacted by phone, 36 patients had died, 4 refused to participate, and 501 patients completed the phone interview. After the phone interviews and obtaining patients' consent to access their/their relatives' medical records, it was impossible to locate nine medical records in the hospital archives. The final study sample available for the analysis was 528. After data collection and cleaning, one variable describing the 'intubation time' was excluded from the analysis because missing values exceeded 10%.

### **3.2 Baseline and procedural characteristics of the patients**

Patients' baseline characteristics are presented in the Table 1. Of 528 patients included in the sample 407 (77.08%) underwent on-pump and 121 (22.92%) off-pump CABG. More females were in the off-pump than in the on-pump group (24.17% versus 11.58%,  $p=0.001$ ). Patients in the off-pump group were on average 8 years older than those in the on-pump group ( $p<0.001$ ), and were more likely to be unemployed ( $p=0.012$ ). In terms of the past medical history and existing comorbidities, the off-pump group included significantly more patients with

hypertension, cerebrovascular disease, gastrointestinal disease and diabetes. The average EuroSCORE was significantly higher in the off-pump group, indicating a higher surgical risk ( $p=0.001$ ). The groups were similar with respect to smoking status and cardiac status including the left ventricular ejection fraction and past history of MI and PCI.

The off-pump group included more single or two vessel disease patients ( $p<0.05$ ). In both groups, the most frequently operated vessel was the left anterior descending artery (LAD) followed by the obtuse marginal 1 (OM1) artery.

Hospital length of stay did not differ between the groups, and was 17.1 (34.3) days for on-pump and 15.9 (9.2) days for off-pump group. Aortal clamp was implemented in 59.65% of on-pump cases.

The groups differed significantly in the rates of discharge prescriptions for some medications (Table 2). Patients from off-pump group were more likely to be prescribed calcium channel blockers (CCB) and hypoglycemic drugs, while on-pump patients were more likely to be prescribed angiotensin converting enzyme inhibitors (ACEi)/angiotensin receptor blockers (ARB). In terms of current medications, biguanides for diabetes was higher in the on pump than off-pump group (10.3% versus 2.7%).

### **3.3 In-hospital complications**

In-hospital complications were developed in 98 (24.14%) on-pump patients and 33 (28.10%) off-pump patients with no significant differences between the groups. The type and distribution of

complications are presented in Table 3. The most common reported complication was arrhythmia, which was significantly higher ( $p=0.016$ ) in the off-pump (26.45%) group than in on-pump (17.24%) group. Other reported complications did not differ between the groups.

### **3.4 Development of major cardiac and cerebrovascular events after surgery**

The average follow-up time was 58.5 (SD=12.9) months for the full sample: 58.2 (SD=13.0) months for the on-pump and 59.5 (12.6) months for the off-pump group ( $p=0.344$ ). The total number of MACCE was 77(14.58%) during the follow up period (Table 4).

### **3.5 Quality of life after CABG**

The by-item analysis of EQ-5D-5L questionnaire showed significantly worse results for the off-pump group regarding mobility, self-care, and doing usual activities (Table 5). No differences were observed in domains of anxiety/depression and pain/discomfort. The patients' overall health status estimated from the visual analogue scale also showed no significant differences between the groups.

### **3.6 Multivariable Cox proportional hazards model**

The univariate Cox proportional hazards model was used to identify the unadjusted baseline predictors of long-term survival from MACCE (Table 6a): Hypertension, EuroSCORE, Ramus, OM1, and LAD were significant MACCE predictors ( $p<0.05$ ). The final model was adjusted for EuroSCORE and diabetes (Table 6b). After adjusting for these covariates, the hazard of developing MACCE did not differ between on-pump and off-pump groups (HR=0.96 for on-pump versus off-pump, 95% CI: 0.56-1.65). After adjusting for diabetes and CBP status (on-

pump versus off-pump), however, each unit of EuroSCORE significantly increased the hazard of MACCE by 1.12 (95%CI: 1.03-1.22). Adjusted for CBP status and EuroSCORE patients with diabetes had higher hazard of developing MACCE than those without diabetes (HR= 1.71, 95%CI: 1.03-2.84).

#### **4. Discussion**

The study evaluated the differences in 5-year event-free survival from MACCE and quality of life in patients who underwent either on-pump or off-pump CABG at NMMC between 2009 and 2010, Yerevan, Armenia. A retrospective cohort study design was utilized for the study where patient baseline characteristics were abstracted from the medical records and post-surgical events established through patient surveys. The final sample included 528 patients of which 23% had off-pump CABG.

We found that at index hospitalization for CABG, on-pump and off-pump patients had different baseline profiles. For example, patients in the off-pump CABG group were on average 8 years older, had higher EuroSCORE, and higher prevalence of hypertension, diabetes, and cerebrovascular disease than those in the on-pump group. This finding is consistent with current guidelines that recommend that off-pump CABG should be used only for patients that are at higher risk of complications from CPB, are older, and/or have multiple comorbidities. <sup>(26-28)</sup> In our study the number of patients with one-vessel and two-vessels disease was higher in the off-pump group while the number of patients with three-vessel disease was higher in the on-pump group. A similar distribution of the number of diseased vessels was observed in the study

conducted by Chawla et al that enrolled a nationally representative patient cohort of 742,909 non-emergent, isolated CABG at 1000 US centers.<sup>51</sup>

According to the literature, off-pump CABG reduces hospital length of stay as a result of avoidance of CBP and its complications.<sup>23</sup> However, our findings showed no significant differences in hospital length of stay. In another study, the mean length of hospital stay was higher in on-pump group only for males and not for females.<sup>52</sup>

Our study found that at 5-year follow-up, MACCE is similar between the on-pump and off-pump CABG groups (HR =0.96, 95%CI: 0.56-1.65). This finding agrees with the systematic reviews by Møller et al and Takagi et al.<sup>37 38</sup> Furthermore, in multivariable analysis we found that diabetes increased the hazard of developing MACCE, which is inconsistent with the results of the study conducted by Lamy et al, where diabetes was not reported as a significant predictor.<sup>53</sup> In this study, EuroSCORE, as an established risk-adjustment score for post-operative mortality, was predictive of long-term MACCE outcomes, similar to findings in the literature.<sup>54</sup> Patients in the off-pump group had higher EuroSCORE (e.g., higher surgical risk), as was found in a trial by Zembala et al.<sup>55</sup>

A previous study conducted at NMMC in 2006 that evaluated the predictors of morbidity and intensive care unit length of stay after CABG reported findings that are similar to the current study.<sup>13</sup> For example, EuroSCORE and diabetes were established as predictors of the intensive care unit length of stay, and arrhythmia was reported as the most frequent postoperative



complication, as in our study.<sup>13</sup> The majority of that study's population was male with high prevalence of hypertension and previous MI.<sup>13</sup>

Although the quality of life was worse for off-pump group patients in terms of mobility, self-care, and doing usual activities, the overall health status reported by the patients was similar between the groups, which replicates other studies' findings.<sup>23,53</sup>

One potential limitation of the study is retrospective data collection through telephone interviews, which may lead to recall bias. Although the self-reported postoperative re-hospitalization/treatment of the patients was double-checked using the electronic database of NMMC in order to minimize this bias, not all readmissions of these events were at NMMC.

Another limitation was the potential inaccuracy of the information in the electronic database and patient medical records, resulting in missing information in some variables. Nearly half of the original patient sample was impossible to contact as a result of inaccurate or missing contact information.

The study was conducted in a single center, potentially limiting the generalizability of the findings to other centers. However, NMMC is the oldest and one of the largest cardiac surgery centers in Armenia, one where cardiac patients are more likely to be representative of the whole Armenian population. Furthermore, the existence of an electronic database and more structured medical records in the center makes the study findings more reliable and accurate. Another major strength of the study was the blinded outcome assessment, as the interviewer did not know to which group the patient belongs, when conducting the interview.

## **Conclusion and recommendations**

The current study assessed 5-year event-free survival among patients who had undergone either on-pump or off-pump CABG. The hazard of developing MACCE was similar between the groups. Diabetes and EuroSCORE are independent predictors of MACCE. Considering the results and the fact that both of the surgery types are still in use, more studies are needed to show the advantages and disadvantages of each type for specific patient populations.

Past studies have shown that off-pump CABG outcomes depend highly on the technical skills of the surgeons, as it is performed on the beating heart.<sup>56,57</sup> The latter makes it more difficult to perform anastomoses, affecting the degree of completeness of revascularization and its overall quality. We were unable to evaluate the effect of the surgical skills on CABG outcomes in our study, and further research is needed to establish how they impact the clinical outcomes after on-pump and off-pump CABG procedures in Armenia. Further research is needed to establish more specific patient eligibility criteria. Future studies should also compare differences in clinical outcomes between different cardiac surgical centers in Armenia. Meanwhile, as the on-pump CABG remains the predominant type, off-pump CABG should be used only for cases where CBP is contraindicated, and should be only conducted by highly skilled surgeons. The results of the current study can be used as a benchmark for further quality improvement interventions.

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## Tables

### Table 1. Patient baseline and procedural characteristics

<b>Characteristics*</b>	<b>On-pump n = 407</b>	<b>Off-pump n = 121</b>	<b>P value</b>
<b><i>Demographic characteristics</i></b>			
Gender			
Male	359 (88.42)	91 (75.83)	0.001
Female	47 (11.58)	29 (24.17)	
Age (years), mean (SD)	61.2 (7.50)	69.5 (8.60)	<0.001
Currently working			
Yes	173 (45.29)	35 (31.82)	0.012
No	209 (54.71)	75 (68.18)	
Income (AMD)			
< 50,000	49 (12.86)	18 (16.36)	0.403
50,001- 100,000	143 (37.53)	45 (40.91)	
100,001-250,000	111 (29.13)	28 (25.45)	
>250,000	52 (13.65)	9 (8.18)	
Don't know	26 (6.82)	10 (9.09)	
<b><i>Risk factors and comorbidities</i></b>			
BMI (kg/m <sup>2</sup> ), mean (SD)	29.1 (4.70)	28.6 (4.80)	0.274
Current smoker			
Yes	100 (26.18)	26 (23.64)	0.591
No	282 (73.82)	84 (76.36)	
Diabetes			0.078
Yes	83 (20.49)	34 (28.10)	
No	322 (79.51)	87 (71.90)	
Hypertension			0.047
Yes	270 (66.50)	92 (76.03)	
No	136 (33.50)	29 (23.97)	
Cerebrovascular disease			
Yes	8 (2.09)	7 (5.79)	0.045
No	397 (97.78)	114 (94.21)	
Gastrointestinal disease			0.233
Yes	56 (13.79)	22 (18.18)	
No	350 (86.21)	99 (81.82)	
Creatinine level (μmol/ L), mean (SD)	90 (20.30)	86.7 (22.90)	0.135
Emergency surgery			
Yes	79 (19.51)	12 (10.08)	0.017
No	326 (80.49)	107 (89.92)	
EuroSCORE, mean (SD)	3.36 (2.24)	4.13 (2.70)	0.001
<b><i>Cardiac status</i></b>			
Stable angina			0.742
Yes	76 (18.67)	21 (17.36)	
No	331 (81.33)	100(82.64)	
Unstable angina			0.713
Yes	289 (71.01)	88 (72.73)	
No	118 (28.99)	33 (27.27)	

History of MI			0.559
Yes	160 (39.31)	44 (36.36)	
No	247 (60.69)	77 (63.64)	
Myocardial infarction			0.105
Acute MI	105 (65.63)	23 (52.27)	
Prior MI	55 (34.38)	21 (47.73)	
Previous PCI			
Yes	34 (8.35)	9 (7.44)	0.746
No	373 (91.65)	112 (92.56)	
LVEF (%), mean (SD)	44.9 (5.40)	45.6 (5.00)	0.246
ICU duration (hours), mean (SD)	68.5 (61.6)	61.2 (26.4)	0.215
Aortic clamp used			<0.001
Yes	241 (59.65)	0	
No	163 (40.35)	113 (100.0)	
Hospital length of stay (days), mean (SD)	17.1 (34.30)	15.9 (9.20)	0.711
<b>Angiographic characteristics</b>			
Number of diseased vessels			
Single	11 (2.71)	8 (6.67)	0.019
Two	43 (10.59)	20 (16.67)	
Three or more	352 (86.70)	92 (76.67)	
Type of operated vessels			
Diagonal1	207 (50.99)	42 (35.00)	0.009
Diagonal2	28 (6.90)	5 (4.17)	0.259
Ramus	93 (22.91)	23 (19.17)	0.584
OM1	277 (68.23)	79 (65.83)	0.507
OM2	69 (17.00)	20 (16.66)	0.476
OM3	7 (1.72)	2 (1.67)	0.999
Distal Circ.	64 (15.76)	10 (8.33)	0.054
L. Post. Lat.	4 (0.99)	5 (4.20)	0.015
R. Post. Lat.	27 (6.65)	6 (5.04)	0.517
Right Main	109 (26.91)	19 (15.97)	0.018
PDA	203 (50.00)	52 (43.33)	0.172
LAD	380 (93.60)	109 (90.83)	0.408
Acute Marginal	9 (2.27)	1 (0.83)	0.610

\*Results are presented as frequencies and percentages, unless specified otherwise.

*BMI: body mass index; LAD: left anterior descending artery; L. Post. Lat.: left posterolateral artery; LVEF: left ventricular ejection fraction; MI: myocardial infarction; OM1, OM2, OM3: obtuse marginal branches; PCI: percutaneous coronary intervention; PDA: posterior descending artery; R. Post. Lat.: Right Posterolateral artery.*

**Table 2. Medication after CABG**

<b>Medications prescribed at discharge</b>	<b>On-pump n = 407</b>	<b>Off-pump n = 121</b>	<b>P value</b>
Antiplatelets	401 (99.01)	117 (98.32)	0.532
BBs	258 (63.70)	76 (63.87)	0.974
ACEi/ARBs	260 (64.20)	59 (49.58)	0.004
CCBs	76 (18.77)	45 (37.82)	<0.001
Glycosides	163 (40.35)	37 (31.09)	0.068
Statins	4 (0.99)	4 (3.36)	0.083
Diuretics	71 (17.53)	21 (17.65)	0.977
Analgesics	383 (94.57)	108 (90.76)	0.132
Antibiotics	170 (41.98)	47 (39.50)	0.629
Hypoglycemic agents	47 (11.66)	23 (19.33)	0.031
Histamine-2 blockers	175 (43.32)	51 (42.86)	0.929
Potassium chloride	62 (15.31)	21 (17.65)	0.539
Anticoagulants	16 (3.94)	10 (8.26)	0.152
Others	34 (8.47)	20 (16.94)	0.001
<b>Medications taken at the time of interview</b>	<b>On-pump n = 382</b>	<b>Off-pump n = 110</b>	<b>P value</b>
Antiplatelets	348 (91.34)	97 (88.18)	0.317
BBs	246 (64.57)	63 (57.27)	0.163
ACEi/ARBs	132 (34.74)	36 (32.73)	0.696
CCBs	58 (15.26)	16 (14.55)	0.853
Diuretics	14 (3.68)	6 (5.45)	0.409
Anticoagulants	25 (6.58)	8 (7.27)	0.798
Statins	122 (32.19)	29 (26.36)	0.244
Biguanides	39 (10.32)	3 (2.73)	0.012

ACEi: angiotensin converting enzyme inhibitors; ARB: angiotensin receptor blockers; BB: beta-blockers; BMI: body mass index; CCB: Calcium channel blockers

**Table 3. In-hospital complications after CABG**

	<b>On-pump n = 407</b>	<b>Off-pump n = 121</b>	<b>P value</b>
<b>In-hospital complication (any), n (%)</b>			
Yes	98 (24.14)	34 (28.10)	0.377
No	308 (75.86)	87 (71.90)	
<b>In-hospital complication type</b>			
Death	2 (0.49)	2 (1.65)	0.385
Stroke/TIA	1 (0.25)	0	0.585
Vascular	1 (0.25)	0	0.585
Infection	9 (2.21)	2 (1.65)	0.706
Respiratory	12 (2.95)	1 (0.83)	0.186
Arrhythmia	68 (17.24)	32 (26.45)	0.016
Other	12 (2.95)	2 (1.65)	0.436

*TIA: transient ischemic attack*

**Table 4. Distribution of major cardiac and cerebrovascular events between on-pump and off-pump groups**

<i>n</i> of patients with events (%)	<b>On-pump n = 407</b>	<b>Off-pump n = 121</b>	<i>P</i> value
MI	3 (0.79)	1(0.91)	0.638
RR			
Stenting	16 (4.19)	2 (1.82)	0.207
CABG	0	1 (0.91)	0.224
Stroke/TIA	12 (3.14)	6 (5.45)	0.255
Death	25 (6.14)	11 (9.09)	0.259
<b>Total <i>n</i> of patients with MACCE*</b>	<b>56 (13.76)</b>	<b>21 (17.36)</b>	<b>0.325</b>

*CABG: coronary artery bypass surgery; MACCE: major adverse cardiac and cerebrovascular events; MI: myocardial infarction; TIA: transient ischemic attack*

*\*Only one patient in the study developed more than one event.*

**Table 5. Quality of life at the time of follow-up interview**

<b>EQ-5D Domains and items</b>	<b>On-pump n = 382</b>	<b>Off-pump n = 110</b>	<b>P value</b>
<b>Mobility/Walking about</b>			
No problems	151 (39.53)	30 (27.27)	0.041
Slight Problems	57 (14.92)	20 (18.18)	
Moderate Problems	119 (31.15)	40 (36.36)	
Severe Problems	47 (12.30)	17 (15.45)	
Unable to do	8 (2.09)	3 (2.73)	
<b>Self-care/washing or dressing yourself</b>			
No problems	270 (70.68)	65 (59.09)	0.020
Slight Problems	65 (17.02)	22 (20.00)	
Moderate Problems	34 (8.90)	18 (16.36)	
Severe Problems	9 (2.36)	3 (2.73)	
Unable to do	4 (1.05)	2 (1.82)	
<b>Doing usual activities</b>			
No problems	143 (37.43)	31 (28.18)	0.049
Slight Problems	79 (20.68)	27 (24.55)	
Moderate Problems	121 (31.68)	32 (29.09)	
Severe Problems	27 (7.07)	15 (13.64)	
Unable to do	12 (3.14)	5 (4.55)	
<b>Pain/discomfort</b>			
No problems	132 (34.55)	33 (30.00)	0.134
Slight Problems	63 (16.49)	18 (16.36)	
Moderate Problems	126 (32.98)	32 (29.09)	
Severe Problems	57 (14.92)	25 (22.73)	
Unable to do	4 (1.05)	2 (1.82)	
<b>Anxiety/depression</b>			
No problems	178 (46.60)	50 (45.45)	0.097
Slight Problems	98 (25.65)	19 (17.27)	
Moderate Problems	82 (21.47)	27 (24.55)	
Severe Problems	21 (5.50)	13 (11.82)	
Unable to do	3 (0.79)	1 (0.91)	
<b>Current health status, mean VAS (SD)</b>	<b>59.8 (18.50)</b>	<b>57.5 (15.10)</b>	<b>0.222</b>

VAS: visual analogue scale.

**Table 6a. Univariate survival analysis for MACCE**

<b>Variable</b>	<b>Hazard Ratio</b>	<b><i>p</i>-value</b>	<b>95% CI</b>
On-pump	0.87	0.596	(0.51 1.46)
Male	0.78	0.426	(0.42 1.43)
Age, years	0.99	0.985	(0.96 1.03)
BMI,kg/m <sup>2</sup>	1.02	0.271	(0.97 1.07)
Diabetes	1.63	0.053	(0.99 2.68)
Hypertension	1.97	0.026	(1.08 3.61)
Cerebrovascular disease	1.55	0.457	(0.48 4.92)
GI disease	1.38	0.287	(0.75 2.53)
Emergency surgery	1.24	0.466	(0.69 2.23)
EuroSCORE	1.10	0.015	(1.01 1.19)
Stable angina	0.79	0.493	(0.42 1.51)
Unstable angina	0.81	0.422	(0.49 1.34)
History of MI	1.06	0.795	(0.66 1.70)
Acute MI	1.36	0.441	(0.62 2.99)
Previous PCI	1.25	0.562	(0.57 2.74)
LVEF, %	0.96	0.103	(0.92 1.00)
Three or more vessels	1.49	0.287	(0.71 3.11)
Creatinine level, µmol/ L	1.00	0.067	(0.99 1.01)
Ramus	2.01	0.005	(1.23 3.27)
OM1	1.91	0.026	(1.08 3.37)
LAD	0.39	0.004	(0.20 0.74)

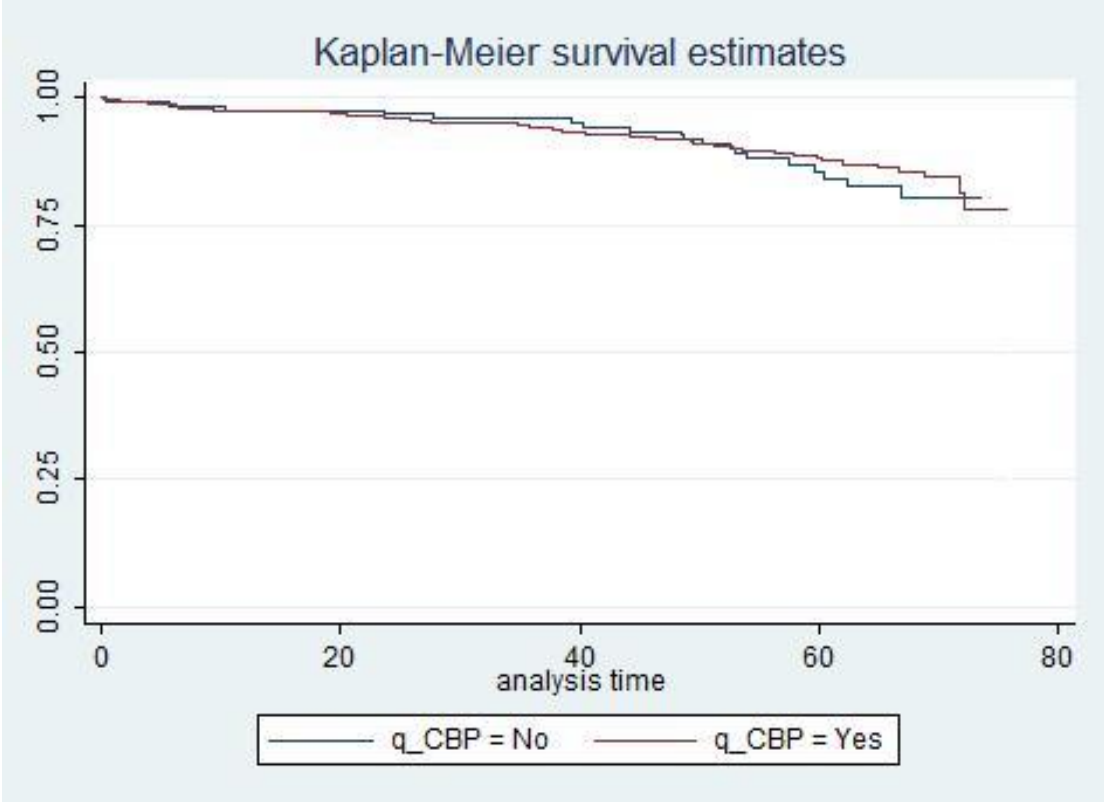
*BMI: body mass index; CBP: cardiopulmonary bypass; GI: gastrointestinal; LAD: left descending artery; MI: myocardial infarction; OM: obtuse marginal; PCI: percutaneous coronary intervention*



**Table 6b. Multivariable Cox proportional hazards model for MACCE**

<b>Variable</b>	<b>Hazard Ratio</b>	<b><i>p</i>-value</b>	<b>95% CI</b>
On-pump	0.96	0.907	(0.56 1.65)
EuroSCORE	1.12	0.007	(1.03 1.22)
Diabetes	1.71	0.036	(1.03 2.84)

**Figure 1. Event-free survival from MACCE by CBP status (unadjusted)**



## Appendices

### Appendix 1. Journal form for the telephone survey

ID	Interview Date	Surgery Date	Disposition Codes	Other

Options for “Disposition Codes”

1. Valid response (Complete survey was received)
2. Incomplete response (Participant refuses to fully complete the survey)
3. Refusal (Participant refuses to complete the survey)
4. Absent from the country
5. Impossible to contact (temporary disconnect/no answer)
6. Dead

Option for “Other”

- Date of death

**Appendix 2. Medical record data abstraction form**

Demographic Characteristics/Surgery data	
<b>1. ID#</b> _____	<b>2. Name</b> _____
<b>3. Gender</b> 0. Female <input type="checkbox"/> 1. Male <input type="checkbox"/>	
<b>4. Date of birth</b> ___/___/___ (dd/mm/yy)	
<b>5. Date of hospital admission</b> ___/___/___ (dd/mm/yy)	
<b>6. Date of discharge</b> ___/___/___ (dd/mm/yy)	
<b>7. Date of surgery</b> ___/___/___ (dd/mm/yy)	
<b>8. ICU stay duration</b> _____(hours)	
<b>9. Intubation period</b> ___:___(hours/minutes)	
<b>10. CBP</b> 0.No <input type="checkbox"/> 1.Yes <input type="checkbox"/>	
<b>11. CBP duration</b> _____ (minutes)	
<b>12. Aortal Clamp</b> 0.No <input type="checkbox"/> 1.Yes <input type="checkbox"/>	
<b>13. Clamp time</b> _____ (minutes)	
<b>14. Inotropic drug use after the surgery</b> 0.No <input type="checkbox"/> 1.Yes <input type="checkbox"/> Please specify: Dopamine <input type="checkbox"/> , Epinephrine <input type="checkbox"/> , Mezaton <input type="checkbox"/> , Milrinon <input type="checkbox"/>	
<b>15. Emergency</b> 0.No <input type="checkbox"/> 1.Yes <input type="checkbox"/>	
Cardiac Status	
<b>16. Stable angina</b> 0.No <input type="checkbox"/> 1.Yes <input type="checkbox"/>	
<b>17. Unstable angina</b> 0.No <input type="checkbox"/> 1.Yes <input type="checkbox"/> (Rest angina requiring iv nitrates until arrival in the anesthetic room)	
<b>18. Myocardial infarction</b> 0.No <input type="checkbox"/> 1.Yes <input type="checkbox"/> , If yes MI onset time 1. At the time of admission <input type="checkbox"/> 2. In the past <input type="checkbox"/>	
<b>19. Heart failure</b> 0.No <input type="checkbox"/> 1.Yes <input type="checkbox"/> If Yes→ NYHA class. 1. <input type="checkbox"/> I 2. <input type="checkbox"/> II 3. <input type="checkbox"/> III 4. <input type="checkbox"/> IV	
<b>20. Ejection fraction</b> 1. Good (LVEF >50%) <input type="checkbox"/> 2. Moderate (LVEF 31%-50%) <input type="checkbox"/> 3. Poor (LVEF 30% or less) <input type="checkbox"/>	
<b>20a. LVEF%</b> _____	
<b>21. Preoperative arrhythmia</b> 0.No <input type="checkbox"/> 1.Yes <input type="checkbox"/> If Yes, Type of arrhythmia _____	
<b>22. Preoperative cardiogenic shock</b> 0.No <input type="checkbox"/> 1.Yes <input type="checkbox"/>	
CAD Risk Factors and Comorbidities	
<b>23. Smoking at the time of admission</b> 0.No <input type="checkbox"/> 1.Yes <input type="checkbox"/>	
<b>24. BMI</b> _____ (W: _____ kg H: _____ cm)	
<b>25. Hypertension</b> 0.No <input type="checkbox"/> 1.Yes <input type="checkbox"/>	

<b>26. Diabetes</b> 0.No <input type="checkbox"/> 1.Yes <input type="checkbox"/>
<b>27. GI disease</b> 0.No <input type="checkbox"/> 1.Yes <input type="checkbox"/>
<b>28. Cerebrovascular disease (stroke/TIA)</b> 0.No <input type="checkbox"/> 1.Yes <input type="checkbox"/>
<b>29. Family history of CAD</b> 0.No <input type="checkbox"/> 1.Yes <input type="checkbox"/>
<b>30. Hypercholesterolemia</b> 0.No <input type="checkbox"/> 1.Yes <input type="checkbox"/>
<b>31. Creatinine &gt; 200 µmol/ L or &gt; 2.26 mg/dL</b> 0.No <input type="checkbox"/> 1.Yes <input type="checkbox"/> (Serum creatinine > 200 micromol/ L or > 2.26 mg/dL preoperatively)
<b>32. Extracardiac arteriopathy</b> (one or more of the following: carotid occlusion or >50% stenosis, claudication, previous or planned intervention on the abdominal aorta, amputation for arterial disease, limb arteries or carotids) 0.No <input type="checkbox"/> 1.Yes <input type="checkbox"/>
<b>33. Neurological dysfunction</b> 0.No <input type="checkbox"/> 1.Yes <input type="checkbox"/> (Severity affecting ambulatory or day-to-day functioning)
<b>34. Chronic lung disease (COPD)</b> 0.No <input type="checkbox"/> 1.Yes <input type="checkbox"/> (Long-term use of bronchodilators or steroids for lung disease)
<b>35. Active endocarditis</b> (Patient still under antibiotic treatment for endocarditis at the time of surgery) 0.No <input type="checkbox"/> 1.Yes <input type="checkbox"/>
<b>36. Critical preoperative state</b> 0.No <input type="checkbox"/> 1.Yes <input type="checkbox"/> (Any one or more of the following: ventricular tachycardia or fibrillation or aborted sudden death, preoperative cardiac massage, preoperative ventilation before arrival in the anesthetic room, preoperative inotropic support, intraaortic balloon counter pulsation or preoperative acute renal failure (anuria or oliguria<10 ml/hour)
<b>37. Other than isolated CABG</b> 0.No <input type="checkbox"/> 1.Yes <input type="checkbox"/> (Major cardiac procedure other than or in addition to CABG)
<b>38. Surgery on thoracic aorta</b> 0.No <input type="checkbox"/> 1.Yes <input type="checkbox"/> (For disorder of ascending, arch or descending aorta)
<b>39. Postinfarct septal rupture</b> 0.No <input type="checkbox"/> 1.Yes <input type="checkbox"/> (Post myocardial infarction septal rupture)
<b>40. Previous PCI</b> 0.No <input type="checkbox"/> 1.Yes <input type="checkbox"/>
<b>41. Previous cardiac surgery</b> 0.No <input type="checkbox"/> 1.Yes <input type="checkbox"/> (requiring opening of the pericardium)
<b>Other Clinical factors</b>
<b>42. Number of diseased vessels</b> 1. Single <input type="checkbox"/> 2. Two <input type="checkbox"/> 3. Three vessels or more <input type="checkbox"/>
<b>43. Type of the diseased vessels (mark all that apply)</b> 1. Diagonal <sub>1</sub> <input type="checkbox"/> 8. Distal Circ. <input type="checkbox"/> 2. Diagonal <sub>2</sub> <input type="checkbox"/> 9. L.Post Lat. <input type="checkbox"/> 3. Diagonal <sub>3</sub> <input type="checkbox"/> 10. R.Post Lat. <input type="checkbox"/> 4. Ramus <input type="checkbox"/> 11. Right main <input type="checkbox"/> 5. OM <sub>1</sub> <input type="checkbox"/> 12. PDA <input type="checkbox"/> 6. OM <sub>2</sub> <input type="checkbox"/> 13. LAD <input type="checkbox"/> 7. OM <sub>3</sub> <input type="checkbox"/> 14. Acute marginal <input type="checkbox"/>
<b>44. Blood Transfusion (intraoperative and postoperative)</b> 0.No <input type="checkbox"/> 1.Yes <input type="checkbox"/>
<b>45. In hospital complications</b> 1. Death <input type="checkbox"/>

- 2. Recurrent MI
- 3. Stroke/TIA
- 4. GI bleeding
- 5. Vascular Complication
- 6. Infection
- 7. Respirator Failure (prolonged intubation, pneumonia, pneumothorax, ARDS)
- 8. Arrhythmia
- 9. Other \_\_\_\_\_

**46. Medication at discharge**

- 1. Aspirin
- 2. B-blockers
- 3. ACE-i/ARB
- 4. Clopidogrel
- 5. Statins
- 6. Other \_\_\_\_\_

**47. EuroSCORE** \_\_\_\_\_

**Appendix 3A. Patient questionnaire (English)**

<b>Health Related Quality of Life</b>						
Questionnaire # _____ ID# _____ Start time of the interview (hours/minutes) _____						
Day of the interview (day/month/year) _____ End time of the interview (hours/minutes) _____						
<b>Describing your health today</b>						
<i>Dear _____ first I am going to ask you few questions about your health.</i>						
<b>Under each heading, please indicate whether you have any problems with conducting the following daily activities by choosing the response that best describes your health today.</b>						
#		No problems	Slight problems	Moderate problems	Severe problems	Unable to do
1.	<b>Mobility</b> (Walking about)	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
2.	<b>Self-care</b> (Washing or dressing yourself)	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
3.	<b>Doing your usual activities</b> (e.g. work, study, housework, family or leisure activities)	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
<b>Please, indicate how you feel regarding the following concerns.</b>						
#		None	Slight	Moderate	Severe	Extreme
4.	<b>Pain/discomfort</b>	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
5.	<b>Anxiety/ Depression</b>	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
<b>Now, we would like to know how good or bad your health is TODAY</b>						
6.	Please imagine a thermometer that is marked from 0 to 100, where 100 is the best state you can imagine and 0 is the worst state you can imagine. <b>What number would indicate how good or bad is your health today?</b> _____					
<b>Now, we would like to ask how you feel and how things have been after you underwent CABG.</b>						
7.	<b>Are the results from your heart CABG operation:</b> Worse than you expected <input type="checkbox"/> About what you expected <input type="checkbox"/>					

	Better than you expected <input type="checkbox"/>		
<b>8.</b>	<b>Are you currently smoking?</b> No <input type="checkbox"/> Yes <input type="checkbox"/> If yes, how many cigarettes per day and for how long time. 1. <10cig/day <input type="checkbox"/> 2. 10-20cig/day <input type="checkbox"/> 3. 20-30cig/day <input type="checkbox"/> 4. >30cig/day <input type="checkbox"/> _____ Years		
<b>9.</b>	<b>During the last 7 days, on how many days did you walk for at least 10 minutes at a time?</b> Days per week _____ Don't Know/Not Sure <input type="checkbox"/>		
<b>10.</b>	<b>How much time did you usually spend walking on one of those days?</b> Hours per day __ __ Minutes per day __ __ __ Don't Know/Not Sure <input type="checkbox"/>		
<b>11.</b>	<b>We want to know if after the operation at the NMMC till now you had ANY hospital admissions for:</b> No <input type="checkbox"/> Yes <input type="checkbox"/> , If yes, please specify the reason and the approximate date(s):		
	<b>Reason(s)</b>	<b>Date(s) (dd/mm/yy)</b>	<b>Hospital</b>
	MI		
	Repeat CABG		
	Stenting		
	Stroke		
	Other reason(s)		
	Specify _____		
<b>12.</b>	<b>What are the medications you are currently taking?</b>		



	<b>1. Aspirin</b> No <input type="checkbox"/> Yes <input type="checkbox"/>
	<b>2. BB</b> No <input type="checkbox"/> Yes <input type="checkbox"/>
	<b>3. ACEi/ARB</b> No <input type="checkbox"/> Yes <input type="checkbox"/>
	<b>4.LL</b> No <input type="checkbox"/> Yes <input type="checkbox"/>
	<b>5.Other</b> _____ _____ No <input type="checkbox"/> Yes <input type="checkbox"/>
	<b>13. Are you currently working?</b> No <input type="checkbox"/> Yes <input type="checkbox"/>
	<b>14. From the following categories which one best describes your household total monthly income in 2009/2010?</b> 1. < 50,000 AMD <input type="checkbox"/> 2. 50,000 – 100,000 AMD <input type="checkbox"/> 3. 101,000 -250,000 AMD <input type="checkbox"/> 4. > 250,000 AMD <input type="checkbox"/> 5. Don't know <input type="checkbox"/> 6. Relatives help <input type="checkbox"/>

**Appendix 3A. Patient questionnaire (Armenian)**

Հարցաթերթիկ առողջության վերաբերյալ						
Հարցաթերթիկ # _____ SՀ # _____ Հարցման ակտիվ (Ժամ/րոպե) _____  Հարցման ամսաթիվը (օր/ամիս/տարի) _____ Հարցման ավարտը (Ժամ/րոպե) _____						
Ձեր առողջության նկարագրումն այսօր						
Հարգելի _____, առջին հերթին ես կհարցնեմ Ձեր բնդհանուր առողջական վիճակի մասին:						
Յուրաքանչյուր հարցում, խնդրում եմ նշեք, արդյոք ունեք որևէ խնդիրներ կապված նշված առօրյա գործողությունների հետ, նշելով այն պատասխանը որը Լավագույնս նկարագրում է Ձեր առողջական վիճակն ՄՅՍՕԲ:						
#		Խնդիրներ չունեք	Փոքր խնդիրներ ունեք	միջին չափի արտահայտված խնդիրներ ունեք	ուժեղ արտահայտված խնդիրներ ունեք	անկարող եք անել
1.	ՇԱՐԺՈՒՆԱԿՈՒԹՅՈՒՆ (քայլել (ման գալ))	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
2.	ԻՆՔՆԱԽԱՍՔ (վագվել /լողանալ կամ հագնվել)	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
3.	ՍՈՎՈՐԱԿԱՆ ԱՌՕՅԱ ԳՈՐԾԵՐ ԿՍՏԱՐԵԼ (օր. աշխատանքի, ուսման, տան, ընտանիքի կամ Ժամանցի հետ կապված գործեր)	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4

**Խնդրում եմ նշեք, ինչպես եք Ձեզ զգում կապված հետևյալ խնդիրների հետ:**

#		չ ու ն ե մ	ու ո ն ե մ մ ի փոքր	ու ո ն ե մ մ ի ջ ի ն չ ափի	ու ո ն ե մ ու ժ ե ղ ար տահ այ տվ ա ծ	ու ո ն ե մ ծ այ ր ա հ ե ղ ար տահ այ տվ ա ծ
4.	ՑԱՎ(ԵՐ)/ՖԻԶԻԿԱԿԱՆ ՏՀԱՃ ԶԳԱՅ ՈՂՈՒԹՅ ՈՒՆ(ՆԵՐ)	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
5.	ՏԱԳՆԱՊ/ԴԵՊՐԵՍԻԱ (ը ն կ ճ վ ած ու թ յ ու ն)	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4

**Այժմ, մենք կցանկանայինք իմանալ, թե որքան լավ կամ վատ է Ձեր առողջական վիճակն ԱՅՍՕՐ:**

6. Խնդրում եմ պատկերացրեք անողորմ համարակալված 0-ից 100 թվերով, որտեղ 100-ը նշանակում է լավագույն առողջական վիճակը՝ Ձեր պատկերացմամբ, իսկ 0-ն նշանակում է վատագույն առողջական վիճակը՝ Ձեր պատկերացմամբ: **Որ թիվը կբնութագրի Ձեր առողջական վիճակն այսօր:**

**Այժմ, մենք ցանկանում ենք հարցնել ինչպես եք Ձեզ զգում վիրահատությունից հետո:**

7. **Ձեր սրտի վիրահատությունից հետո ստացված արդյունքները:**  
 Ձեր սպասված իցավելի վատ է ին   
 Համարյա նույնն է ին ինչ Դուք սպասում էիք   
 Ձեր սպասված իցավելի լավ է ին

8. **Դուք ներկայումս ծխում եք:**  
 Ոչ  Այո   
**Եթե այո, խնդրում եմ նշեք օրական քանի զլանակ եք օգտագործում նորքան ժամանակ:**  
 1. 10-ից քիչ  2. 10-20 զլանակ

	3. 20-30 գլ ան ակ <input type="checkbox"/>	4. >30 գլ ան ակ <input type="checkbox"/>
	_____S ար ի (ն է ր )	
9.	<p>Վե ր ջ ի ն 7 օ ր ու մ , ք ան ի օ ր ե ք Դ ու ք զ ր ո ս ն ե լ /ն տ ք ո վ ք այ լ ե լ ն վ ա զ ա զ ու յ ն ը 10 ր ո ս ե .</p> <p>Շ ա ք ա թ ա կ ան ____ օ ր</p> <p>Չ զ ի տ ե մ /Վ ս տ ա հ չ ե մ <input type="checkbox"/></p>	
10	<p>Ո ր ք ան ժ ա մ ան ակ ե ք Դ ու ք ծ ա խ ս ե լ զ ր ո ս ն ե լ ու /ն տ ք ո վ ք այ լ ե լ ու վ ր ա այ դ օ ր ե ր ի ն 1 օ ր վ ա ը ն թ ա ց ք ու մ :</p> <p>___ ժ ա մ 1 օ ր ու մ</p> <p>___ ր ո ս ե 1 օ ր ու մ</p> <p>Չ զ ի տ ե մ /Վ ս տ ա հ չ ե մ <input type="checkbox"/></p>	
11	<p>Մ ե ն ք ց ան կ ան ու մ ե ն ք ի մ ան ալ ար դյ ո ք Չ ե ր վ ի ր ա հ ա տ ու թ յ ու ն ի ց հ ե տ ո ու ն ե ց ե լ ե ք ո ր ն ի ց ե հ ե տ ա դ ար ձ այ ց հ ո ս պ ի տ ալ ա ց ու մ ո վ , Ս ր տ ա մ կ ան ի Ի ն Ֆ ա ր կ տ ի , կ ն կ ն ա կ ի շ ու ն տ ա վ ո ր մ ան , Ս տ ե ն տ ա վ ո ր մ ան , Ա ն ո թ այ ի ն զ ո ն դ ա վ ո ր մ ան , ի ն ս ու լ տ ի կ ա մ այ լ պ ա տ ճ ա ո ո վ :</p> <p>Ո չ <input type="checkbox"/> Ա յ ո <input type="checkbox"/> , Ե թ ե այ ո , ի ն դ ր ու մ ե մ ն շ ե ք պ ա տ ճ ա ո ը , օ ր ե ր ը ն հ ի վ ան դ ան ո ց ի ան ու ն ը :</p>	
	Պ ա տ ճ ա ո (ն է ր )	Շ ի վ ան դ ան ո ց ի ան ու ն ը
	Օ ր (ե ր ) (օ ր /ա մ ի ս /տ ար ի )	
	Մ Ի	
	Կ ր կ ն ա կ ի շ ու ն տ ա վ ո ր ու մ	
	Ս տ ե ն տ ա վ ո ր ու մ	
	Ա ն ո թ այ ի ն զ ո ն դ ա վ ո ր ու մ	
	Ի ն ս ու լ տ	
	այ լ պ ա տ ճ ա ո (ն է ր ) ն շ ե ք _____	
12	<p>Ի ն չ դ ե դ ո ր այ ք ե ք Դ ու ք այ ժ մ ը ն դ ու ն ու մ .</p> <p>Aspirin _____</p> <p>Ո չ <input type="checkbox"/> Ա յ ո <input type="checkbox"/></p>	

	<b>BB</b> _____ —	Ոչ <input type="checkbox"/> Այո <input type="checkbox"/>
	<b>ACI</b> _____ —	Ոչ <input type="checkbox"/> Այո <input type="checkbox"/>
	<b>LL</b> _____ —	Ոչ <input type="checkbox"/> Այո <input type="checkbox"/>
	<b>Other</b> _____ —	Ոչ <input type="checkbox"/> Այո <input type="checkbox"/>
<b>13</b>	<b>Դուք ներկայումս աշխատում եք:</b>	
.	Ոչ <input type="checkbox"/> Այո <input type="checkbox"/>	
<b>14</b>	<b>Հետևյալ տարբերակներից, որն է ամենաճիշտը նկարագրում Ձեր ընտանիքի ընդհանուր ամսական եկամուտը 2009/2010 թվականին:</b>	
.	1. Ոչ ավելի, քան 50,000 դրամ <input type="checkbox"/>	
	2. 50,000 – 100,000 դրամ <input type="checkbox"/>	
	3. 101,000 -250,000 դրամ <input type="checkbox"/>	
	4. > 250,000 դրամ <input type="checkbox"/>	
	5. Չգիտեմ <input type="checkbox"/>	
	6. Բարեկամներն են օգնում <input type="checkbox"/>	

## **Appendix 4A. Consent form (*English*)**

**American University of Armenia**

**Institutional Review Board #1**

**Consent form for CABG patients**

**Title of research project:** Clinical Outcomes and Quality of Life after Off-pump versus On-pump Coronary Artery Bypass Grafting in Armenia

Hello, my name is Karine Minasyan. I am a second year graduate student at School of Public Health at the American University of Armenia and a medical student at Yerevan State Medical University. As part of my thesis project, and with the support of the faculty members and in collaboration with Nork Marash Medical Center, I am conducting a study to investigate outcomes of patients after coronary artery bypass surgery at the Nork Marash Medical Center. You have been contacted because based on NMMC records you underwent surgery there between 2009 and 2010. Your contact information has been obtained from the NMMC database. If you are willing to participate in this study I will ask you some questions concerning your health. Your participation in the study is voluntary. You may skip any question you think is inappropriate and stop it at any moment you want with no further negative consequences. The interview will take place once at any time that is convenient for you and will last no more than 10 minutes. If you don't mind I will also collect some information from your medical records regarding your health status and interventions.

There will be no monetary benefits for you if you participate in this project. The information provided by you will be very helpful for science and for other patients. There is no penalty for refusing to participate. Whether or not you are in the study will not affect your future treatment at the NMMC. The information provided by you is fully confidential and will be used only for the study. Only aggregate data will be reported.

Contact information will be destroyed upon completion of the research. If you have more questions about this study you can contact Karine Minasyan, the member of the research team – (+37491) 79 39 39, Dr. Varduhi Petrosyan, the Associate Dean of the School of Public Health at AUA calling (+37460) 62 25 64. If you feel you have not been treated fairly or think you have been hurt by joining this study, please contact Dr. Kristina Akopyan, AUA Human Subject Protection Administrator at the American University of Armenia (+374 60) 61 25 61.

If you agree to be involved in this study, could we continue?

**Appendix 4B. Consent form (Armenian)**

**Հայաստանի Ամերիկյան Համալսարան**

**Գիտահետազոտական էթիկայի հանձնաժողով**

**Իրազեկ համաձայնության ձև աորտա-կորոնար շունտավորված հիվանդների համար Հետազոտության վերնագիրը.** Կլինիկական արդյունքները եւ կյանքի որակը առանց արյան արհեստական շրջանառության աորտա-կորոնար շունտավորումից հետո ի տարբերություն արյան արհեստական շրջանառությամբ աորտա-կորոնար շունտավորման Հայաստանում

Բարև Ձեզ, իմ անունը Կարինե Մինասյան է: Ես Հայաստանի Ամերիկյան համալսարանի Հանրային Առողջապահության բաժնի և Երեւանի Պետական Բժշկական համալսարանի մագիստրատուրայի երկրորդ տարվա ուսանող եմ: Ես, որպես իմ ավարտական գիտական աշխատանքի մի մաս, հետազոտական խմբի անդամ դասախոսների աջակցությամբ եւ Նորք-Մարաշ բժշկական կենտրոնի հետ համատեղ, ես իրականացնում եմ հետազոտություն ուսումնասիրելու հիվանդների 5 տարվա արդյունքները աորտա-կորոնար շունտավորման վիրահատությունից հետո: Դուք ընտրվել եք, որովհետև Նորք-Մարաշ բժշկական կենտրոնում գրանցված տվյալների համաձայն Դուք շունտավորվել եք 2009-ից 2010 տարիների ընթացքում: Ձեր տվյալները վերցվել են ՆՄԲԿ-ից՝ տնօրինության համաձայնությամբ: Եթե Դուք համաձայն եք մասնակցել այս հետազոտությանը, ապա ես Ձեզ կտամ որոշ հարցեր Ձեր առողջության վերաբերյալ: Ձեր մասնակցությունը այս հետազոտությանը կամավոր է: Դուք իրավունք ունեք չպատասխանել այն հարցերին, որոնք Ձեզ կարող են տհաճություն պատճառել կամ դադարեցնել հարցազրույցը ցանկացած պահին՝ առանց որևէ հետագա բացասական հետևանքների: Հարցազրույցը տեղի կունենա մեկ անգամ, Ձեզ առավել հարմար ժամանակ, և կտևի ոչ ավելի քան 10 րոպե: Եթե դեմ չեք, ես Ձեր առողջական վիճակի և միջամտության վերաբերյալ որոշ տեղեկություններ կվերցնեմ հիվանդության քարտից: Այս հետազոտությանը Ձեր մասնակցության դեպքում որևէ դրամական խրախուսանք նախատեսված չէ: Ձեր կողմից տրամադրված տվյալները կլինեն շատ կարևոր գիտական տեսանկյունից և օգտակար կլինեն այլ հիվանդների համար: Հետազոտությանը չմասնակցելու դեպքում Ձեզ ոչ մի բացասական հետևանք չի լինի: Անկախ նրանից Դուք կմասնակցեք այս հետազոտությանը թե ոչ, ոչինչ չի ազդի Ձեր ՆՄԲԿ հետագա այցելությունների վրա: Ձեր կողմից տրամադրված ողջ տեղեկությունները գաղտնի կպահվեն և միայն ընդհանրացված արդյունքները կներկայացվեն զեկույցում: Ձեր անձնական տվյալները անմիջապես կոչնչացվեն հետազոտության ավարտից հետո: Հետազոտության հետ կապված հետագա հարցերի համար կարող եք զանգահարել հետազոտական թիմի անդամ՝ Կարինե Մինասյանին, (+37491) 79 39 39 , ՀԱՀ-ի Հանրային Առողջապահության փոխդեկան՝ Վարդուհի Պետրոսյանին, (+37460) 62 25 64: Ինչպես

նան էթե դուք կարծում եք, որ հետազոտության ընթացքում Ձեզ հետ լավ չեն վերաբերվել և/կամ հետազոտությունը Ձեզ վնաս է հասցրել, կարող եք գանգահարել ՀԱՀ-ի Էթիկայի հանձնաժողովի ադմինիստրատոր Քրիստինա Հակոբյանին, հետևյալ հեռախոսահամարով (+374 60) 61 25 61:

Եթե համաձայն եք մասնակցել այս հետազոտությանը, կարող ենք շարունակել: