

**Percutaneous Coronary Intervention with Drug Eluting Stent
versus Coronary Artery Bypass Surgery in Armenia:
A Cost-Effectiveness Study**

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by

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ABSTRACT

Background: Although coronary artery bypass surgery (CABG) remains the treatment of choice for some types of coronary artery disease (CAD), percutaneous coronary intervention (PCI) specifically with drug-eluting stent (DES) has become the most popular nonmedical treatment method to CAD. The objective of the study was to compare cost-effectiveness of CABG versus PCI with DES among patients treated in the period from 2004 to 2005 years at Nork Marash Medical Center (NMMC) in Armenia.

Methods: We did cost-effectiveness analysis from the perspective of patients treated in the single cardiac surgery center - NMMC. Contact, background and procedural information of patients was collected retrospectively from the medical records. Telephone survey was conducted for the evaluation of major adverse cardiac events (MACEs) and resource utilization. Patients who were more than 70 years old, who had prior revascularization (CABG or PCI), cardiogenic shock, end-stage renal disease (serum creatinine level >2 mg/dl), severe left ventricular dysfunction, or cancer at the time of admission were excluded from the sample. We also excluded patients whose procedures were covered by the Ministry of Health of Armenia and third party payers (TPP). NMMC price lists were used to calculate costs of utilized services.

Results: The total number of patients was 124 or 62 in each group. The adjusted difference in number of MACEs between CABG and PCI was -0.29 (95% CI: -0.49 -0.10). The adjusted difference in costs of CABG and PCI was \$USD -1896.61 (95% CI: -2956.57 -836.63). The CABG was the dominant strategy.

Conclusion: Based on the study results, the CABG is more cost-effective than the PCI having lower number of MACEs in terms of repeat revascularization (RR), myocardial infarction (MI) and death and offering lower costs.

INTRODUCTION

Coronary artery bypass surgery and percutaneous coronary interventions present important and established modalities of myocardial revascularization in patients with CAD (15). Although CABG remains the treatment of choice for certain types of CAD, PCI with DES has become the most popular treatment method to CAD (6). Research studies found that the main reasons for a physician to favor CABG over stent were patient factors like left main artery stenosis, total coronary occlusion, ejection fraction less than 25%, small coronary arteries, angioplasty failure, and the need for a combined surgical procedure (18). Diabetes mellitus is another important factor favoring CABG over PCI with stent (18). A more rapid progression of the disease in diabetics may have an unfavorable impact on the outcomes in patients treated with percutaneous techniques compared with CABG (19).

The major concern for PCI with stents is the risk of restenosis that may require repeat revascularizations (RR). The problem was more obvious with bare-metallic stents (BMS). The introduction of DESs promises to further reduce the incidence of restenosis, likely narrowing the gap in late outcomes between PCI and CABG (6). It is estimated that in about 90% of all procedures, PCI now involves stent placement with intense antiplatelet strategies, including dual oral antiplatelet drugs and intravenous glycoprotein IIb/IIIa receptor inhibitors (8). A meta-analysis of 11 randomized clinical trials found that when compared with BMSs, DESs did not have any advantage in terms of MI or mortality but demonstrated decreased rates of angiographic restenosis and MACEs (6). Restenosis still is the major determinant of event-free survival after the DES placement (26).

Several large randomized clinical trials that compared PCI with CABG in multivessel coronary artery disease (MVCD) found that mortality was not significantly different between these strategies after one and five years of follow-up (4,14,17, 24,25,27,28). Mortality ranged from 3.0% in the CABRI trial at 1-year follow-up (PCI versus CABG) and 3.4% in

the RITA trial at 2.5 years (PCI versus CABG) to 13.0% in the BARI trial at 5 years (PCI versus CABG) (18). A slightly higher incidence of MI was noted in some of these trials (PCI versus CABG) (18). The Arterial Revascularization Therapy Study (ARTS) was designed to compare the CABG and the PCI with stenting for the treatment of patients with MVCD (19). One year after the procedure, coronary stenting demonstrated a substantial reduction in costs due to 14.4% lower rate of major adverse cardiac and cerebrovascular events (MACCEs) (19). However, the authors concluded that beyond the first year, the initial favorable cost-effectiveness of the percutaneous approach could decrease with time because the need for late repeat revascularization may be substantially higher after percutaneous procedures in patients with MVCD (19).

The burden of CAD in Armenia is significant as in the most of the world. The National Institute of Health in Armenia reported that 14.1% of all deaths and discharges were attributed to coronary vascular disease CVD (29). According to the European Cardiovascular Disease Statistics 2008, the total proportion of deaths in 2002 in Armenia from CVD was 32.78 % among men and 33.65% among women (1). Coronary Heart Disease (CHD) by itself is the main cause of deaths in Europe: accounting for over 1.92 million deaths each year (1). Over one in five women (22.0%) and men (21.0%) die from the disease (1). According to the same source, in 2006 the cost of CVD to the health care system of the European Union (EU) was just under € 110 billion with productivity losses costing almost €41billion (1). The burden of disease is increasing with the aging population and the increase of prevalence of diabetes mellitus, obesity, and physical inactivity.

The health care system of Armenia is still experiencing several difficulties after the deterioration of the Soviet Union in early 1990s shifting from a centralized state-owned state to the more decentralized, semi-private system. Currently, there are both private and non-private hospitals in Armenia. The majority of centers have their own price lists for the

procedures. In the majority of hospitals services included in the Basic Benefits Package (BBP) for patients with low socio-economic status is covered by the Ministry of Health (29). The expenditures of patients who are working in mining industry covered by the third party payers: at the expense of mining company. The majority of patients, though, pay for their services including direct costs to the hospital, under-the-table payments, medication costs, and travel. The 2006 household survey shows that out of pocket health expenditures remain substantial (22). Armenia spends about 2% of GDP in public funding of health services, has no social health insurance system, and has a minuscule voluntary health insurance industry (22). By comparison, other countries with similarly developed health systems and aging populations spend a minimum of 4 % to 6% of GDP on health from taxes or risk pooling mechanisms (22). The planned increase in public health funding over the next three years does not appear to target the biggest sources of out of pocket expense- hospitals and drugs (22). For the next few years, the Government of Armenia is not planning to increase hospital funding dramatically, so it will likely be difficult to reduce the burden of out of pocket health expenses (22).

Taking into account current poor economic situation in Armenia, relatively expensive treatment options for CAD, and increasing disease prevalence we aimed to perform an economic evaluation of coronary artery revascularization methods. More specifically, the study evaluated whether the PCI with DES is more cost-effective than the CABG in preventing MACEs (composite outcome of MI, RR, and death) after on average four years of procedure among patients with ischemic heart disease treated at NMMC from 2004 to 2005 years. The analysis was done from the patients' perspective treated in a single cardiac surgery center in Armenia. We hoped that the study will improve the decision making of patients, health care providers, and TPP.

MATERIALS AND METHODS

The study enrolled patients who underwent PCI with DES or CABG at the NMMC in Armenia from January 1, 2004 to December 31, 2005. This center was established in 1993 and is currently one of the biggest cardiac surgery centers in Transcaucasian Region (21). Approximately 90% of patients in Armenia receive cardiac surgery in this center, and there are other two centers that perform interventions with lower volumes.

Contact, background and procedural information of patients was collected retrospectively from NMMC medical records. This was followed by a telephone survey of patients from April to June 2009 to identify the MACEs and resource utilization. Study eligibility criteria included only patients residing in Armenia at the time of the survey and speaking Armenian. Patients who were more than 70 years old, who had prior revascularization (CABG or PCI), cardiogenic shock, end-stage renal disease (serum creatinine level >2 mg/dl), severe left ventricular dysfunction (left ventricular ejection fraction <30%), or cancer at the time of admission for the primary intervention were excluded from the sample. We also excluded patients whose procedures were covered by the BBP or TPP.

Standard of care

At the NMMC usually a three-member expert panel including an interventional cardiologist, an invasive cardiologist and a cardiologist evaluates the clinical appropriateness of the bypass surgery or the PCI based on the results of the patient's physical examination, medical history, and patient preferences. Time for recovery, postoperative care, and postoperative pain affect significantly patients' preferences. However, because there is no health care insurance in Armenia and the majority of patients pay for their procedures, current income status and affordability of services are one of the major factors that affect patients' decisions. After the discharge, doctors are prescribing medications to a patient

based on the American Heart Association/American College of Cardiology special guidelines and are encouraged to visit NMMC according to a developed follow-up scheme.

Effectiveness (outcomes) measures

The primary effectiveness measure was the number of MACEs measured as a composite of MI, RR, and death at the end of follow-up. We also evaluated the event-free survival time from any MACE. In addition we reported the number of cerebrovascular accidents.

Resource utilization and costs

For the study purposes, we assumed that all patients who were treated for the major events after the procedure, received care for RR at the NMMC (CABG, PCI, coronary angiography). This was justified by the fact that the majority of patients, once they are treated at the center, prefer to seek their care at the same center after. Since the center is not focused on MI and stroke treatment we used costs for MI and stroke determined by Public Sector Reform Program. The center has a short follow-up insurance policy - the fixed cost of the CABG or PCI paid by the patient also includes a six month of follow-up care after the procedure. Hospital price lists for the corresponding years were used to extract the costs of services. The fixed, aggregate costs paid by the patients to the hospital included the cost of the procedures (PCI or CABG), repeat angiography costs, and medication costs. The study did not consider direct non-medical costs such as transportation, as well as indirect costs in terms of opportunity loss. Because of the relatively short follow-up, we ignored discounting for future benefits and costs. The Armenian national currency (Dram) was transferred into US dollars based on the average exchange rate of the given year obtained from the Armenian Central Bank.

Patient surveys

Using telephone interviews, patients were asked about their general and heart related health, income, smoking status and physical activity, readmission details if any (treatment center, duration, and costs of treatment (both ‘formal’ and ‘non-formal’)) of major adverse cardiac events. We also compared the prescription patterns between two groups comparing prescriptions from medical records and patient reports from interviews.

The research proposal was submitted and reviewed by the Institutional Review Board Number One of the American University of Armenia. Oral consent was obtained from patients prior their participation in the telephone interview (Appendix 5). When the patient to be contacted was identified as deceased by the relative, other than the date and the reason of death no further questioning was attempted and the call was ended after a condolence was expressed.

Statistical considerations

Since the number of patients who had PCI with DES was approximately three times smaller than the CABG patients in the specified period, first we included all PCI patients who met the inclusion criteria and then matched each with three patients from CABG population. From the latter, only the first CABG patients who answered the survey, was included in the analysis. To adjust for major patient baseline factors that play role in selection of the procedures and their effectiveness, PCI and CABG patients were matched on date of birth (± 3 years), gender, and diabetes mellitus status. Baseline data from NMMC medical records and interviews was entered into SPSS 17 software package. Single data entry was performed. Logical and range checks were used to assess the accuracy of data entry. The data analysis was done using Stata10 software package.

Patient baseline characteristics were described using means with standard deviations and frequencies. Baseline characteristics between groups were compared using McNemar's test for dichotomous variables and Wilcoxon Signed Rank test for variables with more than two categories. Variables significant at $p<0.05$ were included in linear regression models to obtain adjusted mean differences in costs of interventions and outcomes (number of MACEs). Uncertainty of finding was explored by displaying 90% CI around the incremental net benefit (INB) for various levels of willingness-to-pay (WTP). The unadjusted event-free survival rates were calculated using the Kaplan-Meier method and were compared by a log-rank test.

RESULTS

Administrative information

There were 142 patients who were residents of Armenia and underwent the PCI/DES in 2004-2005 years in NMMC. However, 14/142 records were not found in the hospital archives. From remaining, 97 people only met the inclusion criteria. Overall, 61 patients were interviewed from 97 yielding a response rate of 62.9%. One patient died after the intervention. The remaining interviews ($n=35$) failed due to the following reasons: were in the hospital ($n=1$), patient refused ($n=3$), paid by BBP ($n=3$), the phone numbers were wrong or impossible to contact ($n=14$), patient was out of country ($n=4$), and nobody answered the phone ($n=10$). Data collection was conducted from March 26 to June 4 in 2009. After PCI patients' interviews and collection of baseline characteristics, the CABG group was sampled following the predefined matching criteria. The total number of patients was 124 or 62 pairs.

Baseline Clinical and Angiographic Characteristics

Patients' baseline characteristics are described in Table 1. The majority of patients in both groups were males ($n= 52$, 83.9%). The youngest patient was 35 and the oldest 68 years old. In both groups, the majority was in age category from 55 to 63 years old (34.7%). Four

persons (6.5%) in each group had DM. Angina was the most prevalent condition (71.8%), followed by MI in the past (29.8%), then AMI (15.3%). Patients who had CABG were more frequently diagnosed with unstable angina than patients who underwent stent replacement ($p=0.0373$).

As it was expected, the angiographic catheterization detected the difference between two groups in the number of diseased vessels, type of vessels, and diffusion. Majority of patients in the PCI group had only two diseased vessels (37.7%), whereas the majority of CABG patients had more than three diseased vessels (51.7%) ($p=0.000$). CABG patients had more diffused vessels (20%, $p=0.0034$). There was a significant difference in the type of diseased vessels between the groups ($p<0.003$). Hypercholesterolemia was diagnosed in 16.1% of patients in CABG group and in 3.2% patients in PCI group ($p<.0386$).

Overall, there were significant differences in the variables describing angina, hypercholesterolemia, number of diseased vessels, type of diseased vessels, and diffused vessels. These variables were used in multiple linear regression analysis to produce adjusted differences in costs and effectiveness.

Follow-up and major adverse cardiac events

The mean duration of the total follow-up period was 1471.726 ± 212.3482 days (median = 1403.5 , $Q_{75} - 1593.75$, $Q_{25} - 1279.5$) in PCI group and 1672.194 ± 216.5514 days (median- 1688.00 , $Q_{75} - 1879.5$, $Q_{25} - 1469$) in CABG group. The total number of MACEs during the follow-up time was 21 (Table 2). During the total follow-up period there were three cases of nonfatal MI, one in the CABG group and two in the PCI group. There were 15 cases of RR: seven patients had stent replacement in the group initially treated by PCI and two in the group initially treated by CABG; six patients from PCI group underwent CABG while no patient had RR with CABG among patients initially treated by CABG. Two patients from CABG and one from PCI died. Overall, 22.6% ($n=14$) of patients in PCI group and 8.1%

(n=5) in CABG group had MACEs – an unadjusted difference of 14.5% with fewer MACEs in CABG group. The unadjusted difference between the number of MACEs was 9. During the telephone interview one patient (1.61%) initially treated with PCI and six patients (9.7%) initially treated with CABG reported a stroke with one of CABG patients reporting two events of stroke.

Figure 1 presents the Kaplan-Meier survival curves for two groups. The log-rank test for equality of survival distribution showed that patients in the CABG group had significantly longer event-free survival times than patients in the PCI group ($p<0.037$, unadjusted difference).

Cost-effectiveness analysis

The mean cost for the initial PCI treatment ($\$4444.0 \pm 108.36$) was much higher than that of for initial CABG ($\$3368.186 \pm 10.62$) in the period from 2004 to 2005 year (Table 3). The total cost of treating MACEs was \$347,331 in PCI group and \$219,693 in CABG group. The unadjusted mean per patient difference in costs was \$2059 with CABG being less costly. After controlling for angina, hypercholesterolemia, number of diseased vessels, type of diseased vessels, and diffused vessels, the adjusted difference in costs of CABG and PCI was \$1896.61 (95% CI: -2956.57 – 836.63) with CABG being less costly (Appendix 8). Based on the regression model, adjusted difference in number of MACEs between CABG and PCI was -0.29 (95%CI: -0.49 – -0.10). These results indicated the dominance of CABG over PCI with DES: CABG was less costly by \$6540 with preventing one more MACE compared to PCI.

We varied the WTP (λ) from \$0 to \$5,000 to receive the INB for different values and the 90% CIs around the results. INB analyses showed that even if a patient does not want to pay for the prevention of any MACE, CABG is still more effective and less costly by \$1,896.6. In case if a patient is willing to pay \$1,000 to prevent one MACE, INB is equal to

\$2,186.6. The INB is positive for any value of WTP including zero (Figure2). Similarly, the cost-effectiveness acceptability curve showed that the probability that CABG is more cost-effective than PCI was 100% for all WTP values.

Other results from the telephone survey

In general, most of the participants were satisfied with their general health in both groups (54.1% in PCI group, 63.3% in CABG group). Those patients that were admitted to the hospital due to AMI had difficulty when asked to compare the health status before and after the intervention. However, many of them indicated that they feel much better after the intervention than before (36.1% in PCI group, 42.4% in CABG group). Smoking characteristics were also similar between the groups. Overall, groups were homogenous in current general health, physical activity level, adherence to medication, employment status, and income (Appendix 6).

Generally, patients who had PCI were prescribed Acetylsalicylic Acid (Cardioaspirin or Cardiomagnil) combined with Ticlid (Ticlopidine) or Plavix (Clopidogrel) for a definite period of time. Patients who had high cholesterol level were recommended to use cholesterol-lowering drugs. After a CABG procedure, patients are prescribed antibiotics for very short period (mostly Ciprofloxacin) then Cardioaspirin/Cardiomagnil, Digoxin and cholesterol-lowering drugs were prescribed by intended use (Table 5).

DISCUSSION

Health technology assessment improves allocation of resources to achieve better results. Cost-effectiveness analysis helps identify neglected opportunities by highlighting interventions that are relatively inexpensive, yet have the potential to reduce the disease burden substantially (9).

To our knowledge, no studies have examined the cost-effectiveness of percutaneous management with DES versus CABG for patients with CAD in Armenia. As ischemic heart disease has high incidence in Armenia and financial burden is not going to be reduced substantially, the study findings provide important information for decision makers such as patients, physicians and TPPs. The importance of our study was also justified by the fact that most of the patients during the telephone interview were interested in our final findings. In this economic study, we found that CABG strategy was dominant over PCI with DES at approximately 4.2 years follow-up period by saving the costs and increasing effectiveness in terms of avoiding MACEs. To prevent one MACE a patient who underwent CABG spent \$6540 less money than patient who underwent PCI. INB analyses strengthen our findings since INB was positive even for the \$0 of WTP for avoiding one MACE.

Recently, the one year results from the ARTS II registry demonstrated that PCI with DES can produce clinical results comparable (or even superior) to those seen with CABG in patients with multivessel coronary artery disease (3, 19). Reynolds and colleagues conducted the study approximately similar to ours, but in contrast, they found that multivessel stenting and CABG result in comparable risks of death and MI (23). Despite a higher rate of RR, multivessel stenting was significantly less costly than CABG through the first 2 years of follow-up (23). Another study conducted by Griffin and colleagues found that in the group rated eligible to either CABG or PCI, bypass surgery had the highest mean quality adjusted life years. The Incremental Cost-Effectiveness Ratio (ICER) of the bypass surgery was £22,000 per quality adjusted life year compared with percutaneous management. The probability that bypass surgery, percutaneous management and medical management are the most cost-effective forms of management was estimated at 63.0% and 22.0% and 15.0% respectively (12).

In countries like Armenia, that does not have centralized system for provision of health care services and patient and physician reimbursement, where the costs of treatment can vary annually and the informal payments are dominated in most of the health care facilities, it is hard to perform any type of economic evaluation. Though NMMC has all information about the follow-up visits after the intervention, some patients prefer to continue their follow-up treatment in other clinics because of waiting-time at NMMC and other reasons.

The PCI with DES in Armenia was introduced in 2003. Based on the Figure 4 illustrated in Appendix 7 we can see that before 2006 prices for DES was higher than prices for CABG and after 2006 CABG was more expensive than treatment with DES. The higher prices for DES in 2004 and 2005 could be attributed to the novelty of the device. This could overestimate the cost for PCI with DES in our results.

Primary Health Care Reform Project in Armenia that conducted survey in 2007 found that financial barriers were the biggest reason that Armenians did not seek medical care (22). Forty seven percent of households not seeking medical care reported that they refrained due to financial reasons (22). During the telephone survey, it was stated by the most of the patients that they feel they need to visit their doctor, to have an examination and maybe have a revascularization, but the high prices and absence of money are constraining them. That is why we decided to exclude repeat coronary angiography and laboratory analysis costs from our study. Based on this we can also imply that low income and high prices are barriers for the repeat revascularizations and may underestimate total costs of each intervention. To report, the distribution of income level was similar between the groups.

The study had several limitations. First, this was a retrospective study and patients were not randomized to ensure comparable patient populations – an important factor considering the extraordinary anatomic and physiologic complexity of CAD (18). Next, it is possible that there were inaccuracies in medical records, which were noted in many other

previous studies. Some screening outcomes were not consistent with diagnosis; for example, a patient who had high level of cholesterol during few screenings was not indicated as having hypercholesterolemia at admission. For blood pressure and left ventricular ejection fraction, we used results from objective examination of a patient after the intervention. Family history of ischemic heart disease and body mass index were excluded from data analyses because of missing data in more than 10% of records. We did not evaluate the quality of life and quality adjusted life years that would give us stronger information about the effectiveness of these treatment methods. We were not able also to control for duration of stenosis and how tight it was before the intervention, an important predictor for restenosis found in many other studies (8, 15). Also all type of diseased vessels was entered into the data, but for analyses, we collapsed them into five categories taking into account more risky vessels. Based on self-reported stroke, experienced by six patients in CABG and one patient in PCI group, we considered the necessity to measure the effectiveness also as major adverse cardiac and cerebrovascular events (MACCE). Countries with similar economic indicators and aging population as in Armenia can use our study results for comparison.

In conclusion, our study found that CABG is a more cost-effective strategy than PCI with DES in terms of preventing RR, MI and death and saving costs. Even if the cost for PCI has decreased after 2006, the effectiveness of bypass surgery was obvious. Prospective evaluation with longer time horizon would add more information to the results of our study. The results of our cost-effectiveness study would be a valuable source for future considerations and policy statements at NMMC. Moreover, since the number of patients referred to the PCI replacement is increasing, the pricing is frequently changing, and there are new technologies in development, the economic evaluations should be considered as a part of quality assessment strategies.

Finally, there is a great need to do economic evaluation of strategies intended to decrease the burden of CAD in Armenia; not only from the perspective of the patients who suffer from the disease and pay for healthy future, but also from the perspective of policy makers who are responsible for effective allocation of resources and substantial gain in public health.

References

- (1) Allender S, Leal J. European Cardiovascular Disease Statistics.2008 edition. 2008.<http://www.eropa.org/a/2920> . Accessed November 15, 2008.
- (2) American Heart Organization page. <http://www.americanheart.org>. Accessed October 15, 2008.
- (3) Bhatt D, Topol E. Debate: PCI or CABG for multivessel disease? Viewpoint: No clear winner in an unfair fight. Current Controlled Trials in Cardiovascular Medicine 2001; 2(6):260-262.
- (4) CABRI trial participants: First-year results of CABRI (Coronary Angioplasty versus Bypass Revascularization Investigation). Lancet 1995; 346:1179
- (5) Chaitman BR, Fisher LD, Bourassa MG, Davis K, Rogers WJ, Maynard C et al. Effect of coronary bypass surgery on survival patterns in subsets of patients with left main coronary artery disease. Report of the Collaborative Study in Coronary Artery Surgery (CASS). Am J Cardiol 1981; 48:765-777.
- (6) Cohen DJ, Krumholz HM, Sukin CA, Ho KK, Siegrist RB, Cleman M et al. In-hospital and one-year economic outcomes after coronary stenting or balloon angioplasty. Results from a randomized clinical trial. Stent Restenosis Study Investigators. Circulation 1995; 92:2480-2487.
- (7) Cura FA, Bhatt DL, Lincoff AM, Kapadia SR, L'Allier PL, Ziada KM et al. Pronounced Benefit of Coronary Stenting and Adjunctive Platelet Glycoprotein IIb/IIIa Inhibition in Complex Atherosclerotic Lesions. Circulation 2000; 102:28-34.
- (8) Cutlip DE, Chhabra AG, Baim DS, Chauhan MS, Marulkar S, Massaro J et al. Beyond Restenosis: Five-Year Clinical Outcomes From Second-Generation Coronary Stent Trials. Circulation 2004; 110(10):1226-1230.
- (9) Dean T, Jamison JG, Breman AG, Measham AR, Alleyne G. Priorities in Health: World Bank Publications; 2006.
http://publications.worldbank.org/ecommerce/catalog/product?item_id=4856041. Accessed October 11, 2008.
- (10) Ferreira AC, Peter AA. Clinical impact of drug-eluting stents in changing referral practices for coronary surgical revascularization in a tertiary care center. Ann Thorac Surg 2003; 75:485– 89.
- (11) Firth BG, Cooper LM, Fearn S. The Appropriate Role Of Cost-Effectiveness In Determining Device Coverage: A Case Study Of Drug-Eluting Stents. Health Aff 2008; 27(6):1577-1586.
- (12) Griffin SC, Barber JA, Manca A, Sculpher MJ, Thompson SG, Buxton MJ et al. Cost effectiveness of clinically appropriate decisions on alternative treatments for angina pectoris: prospective observational study. BMJ 2007; 334(7594):624.

- (13) Grines CL, Cox DA, Stone GW, Garcia E, Mattos LA, Giambartolomei A et al. Coronary angioplasty with or without stent implantation for acute myocardial infarction. Stent Primary Angioplasty in Myocardial Infarction Study Group. N Engl J Med 1999; 341:1949-1956.
- (14) Hamm CW, Reimers J, Ischinger T, Rupprecht HJ, Berger J, Bleifeld W et al. A Randomized Study of Coronary Angioplasty Compared with Bypass Surgery in Patients with Symptomatic Multivessel Coronary Disease. N Engl J Med 1994; 331(16):1037-1043.
- (15) Javaid A, Steinberg DH, Buch AN, Corso PJ, Boyce SW, Pinto Slottow TL et al. Outcomes of Coronary Artery Bypass Grafting Versus Percutaneous Coronary Intervention With Drug-Eluting Stents for Patients With Multivessel Coronary Artery Disease. Circulation 2007; 116(11_suppl):I-200.
- (16) Kastrati A, Schomig A, Elezi S, Dirschinger J, Mehilli J, Schuhlen H et al. Prognostic Value of the Modified American College of Cardiology/American Heart Association Stenosis Morphology Classification for Long-Term Angiographic and Clinical Outcome After Coronary Stent Placement. Circulation 1999; 100(12):1285-1290.
- (17) King SB, Kosinski AS, Guyton RA, Lembo NJ, Weintraub WS. Eight-year mortality in the Emory Angioplasty versus Surgery Trial (EAST). J Am Coll Cardiol 2000; 35:1116-1121.
- (18) Lawrence H. Cohn, MD. Cardiac surgery in the adult. 3th ed. *Ischemic Heart Disease*. McGraw-Hill 2008;22; 549-669
- (19) Legrand VMG, Serruys PW, Unger F, van Hout BA, Vrolinx MCM, Fransen GMP et al. Three-Year Outcome After Coronary Stenting Versus Bypass Surgery for the Treatment of Multivessel Disease. Circulation 2004; 109(9):1114-1120.
- (20) Leon MB, Popma JJ, Mintz GS, Pichard AD, Satler LF, Kent KM. An overview of US coronary stent trials. Semin Intervention Cardiol 1996; 1:247-254.
- (21) Nork Marash Medical Center page. <http://www.nmmc.am>. Accessed February 10, 2009.(29)
- (22) Primary Health Care Reform Project. How Great is the Burden of Household Health Expenditure in Armenia. 2008. <http://www.phcr.am/>. Accessed May 20, 2009.
- (23) Reynolds M, Neil N. Clinical and economic outcomes of multivessel coronary stenting compared with bypass surgery: A single-center US experience. American Heart Journal 2003;145(2); 334-342.
- (24) RITA Trial Participants: Coronary angioplasty versus coronary artery bypass surgery: The Randomized Intervention Treatment of Angina (RITA) trial. Lancet 1993; 341:573.

- (25) Serruys PW, Unger F, Sousa JE, Jatene A, Bonnier HJ, Schon-berger JP et al. Comparison of coronary-artery bypass surgery and stenting for the treatment of multivessel disease. *N Engl J Med* 2001; 344:1117-1124.
- (26) Sidney C. Smith, James T. Dove. A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1993 Guidelines for Percutaneous Transluminal Coronary Angioplasty). *Circulation* 2001;103:3019.
- (27) The Bypass Angioplasty Revascularization Investigation (BARI) Investigators. Comparison of coronary bypass surgery with angioplasty in patients with multivessel disease. *N Engl J Med* 1996; 335:217-225.
- (28) The BARI, I. The Final 10-Year Follow-Up Results From the BARI Randomized Trial. *J Am Coll Cardiol* 2007; 49(15):1600-1606.
- (29) The National Institute of Health. <http://www.niharm.am/IAC.htm>. Accessed November 28, 2008.

Tables and Figures

Table 1. Baseline characteristics

Characteristics	PCI (n=62) n (%)	CABG (n=62) n (%)	P-value
Age categories			
35-45	14 (22.58)	16(25.81)	0.7630
46-54	20 (32.26)	18(27.42)	
55-63	22 (35.48)	22(33.87)	
64-68	6 (9.68)	8 (12.90)	
Number of Diseased Vessels			
Single	20(32.8)	5 (8.3)	0.000
Two	23(37.7)	5 (8.3)	
Three	12(19.7)	19(31.7)	
More than three	6 (9.8)	31(51.7)	
Angina			
No	24(38.71)	11(17.74)	0.0373
Stable	2 (3.23)	7 (11.29)	
Unstable	36(58.06)	44 (70.97)	
Ejection Fraction, %			
<35	14(24.1)	7 (11.7)	0.9437
35-50	33(56.9)	46(76.7)	
>50	11(19.0)	7 (11.7)	
MI			
Yes	20(32.26)	17(27.42)	0.7111
AMI			
Yes	9(14.52)	10(16.13)	1.000
Diseased Vessels			
LCA	18(29.0)	10(16.7)	
RCA	7 (11.3)	1 (1.7)	0.004
LAD+RCA	25(40.3)	23 (38.3)	
LM	2 (3.2)	3 (5.0)	
Left CX	10(16.1)	23(38.3)	
Diffused Vessels	1(1.61)	12(20.0)	0.003
Peripheral Vascular Disease	2(3.23)	1(1.61)	1.000
Hypertension	30(48.39)	37(59.68)	0.2649
Arrhythmia	2(3.23)	-	0.5000
Heart Failure	1(1.61)	-	1.0000
Hypercholesterolemia	2(3.23)	10(16.13)	0.0386
Cerebral Vascular Disease	-	1(1.61)	1.000
Chronic Lung Disease	5(8.06)	4(6.45)	1.000
Renal Dysfunction (Kidney Disease)	4(6.45)	1(1.61)	0.375
Endocarditis	-	-	1.000

Table 2. Major Adverse Cardiac Events

Events	PCI (n=62)		CABG (n=62)	
	# events	n (%)	# events	n (%)
MI	2	2 (3.2)	1	1 (1.6)
RR				
CABG	6	13 (20.97)		2 (3.23)
Stent	7		2	
Death	1	1 (1.6)	2	2 (3.2)
Total number of	16	14 (22.58)	5	5 (8.06)
MACE				

Table 3. Costs

	Unit costs, \$	PCI(n=62)	CABG (n=62)
(2004)			
PCI	\$4,200.00	\$275,565.63	
CABG	\$3,300.00		\$208,827.50
RR			
Stent	\$4,200.00	\$71,238.31	\$10,488.36447
CABG	\$3,300.00		
MI		\$527.68	\$376.925
Death	\$0		
Total cost	-	\$347,331.6	\$219,693.1

Table 4. Adjusted cost and effectiveness estimates of interventions

	Unadjusted difference	Adjusted	95% CI of Adjusted	
		MD*	MD	
Costs	-2058.686	-1896.605	-2956.57	-836.635
Number of MACE	9	-0.29	-0.49	-0.0965

*Adjusted mean difference; adjusted for diffused vessels, number of diseased vessels, and type of diseased vessels, angina, and hypercholesterolemia.

Table 5. Medication prescription after the intervention

Medications	PCI(n=62)	CABG(n=62)	P value
Aspirin	38(79.17)	56(91.80)	0.0923
Cardiomagnil	15(31.25)	13(21.31)	0.5235
Ticlid	21(43.75)	1 (1.64)	0.0000
Plavix	4 (8.3)	2 (3.28)	0.3750
Cholesterol			
Lowering Drugs (Statins)	13(52)	17(27.87)	0.0225
Digoxin	3(4.84)	19(31.15)	0.0001

Figure 1. Major Adverse Cardiac Event Free Survival in two treatment groups

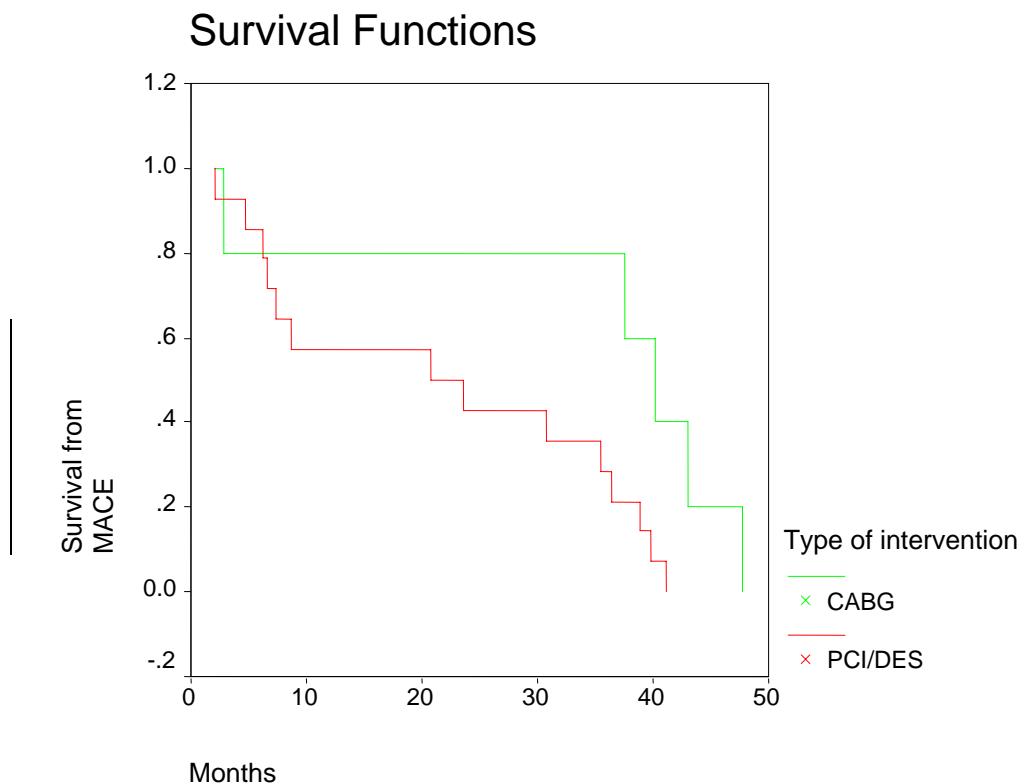


Figure 2. Incremental net benefit for various willingness-to-pay values

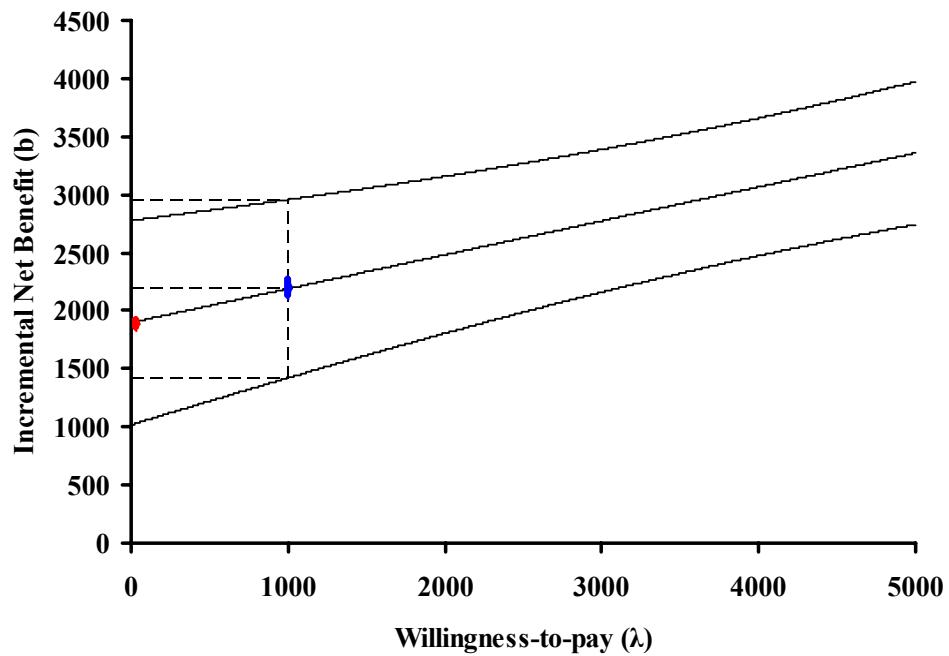
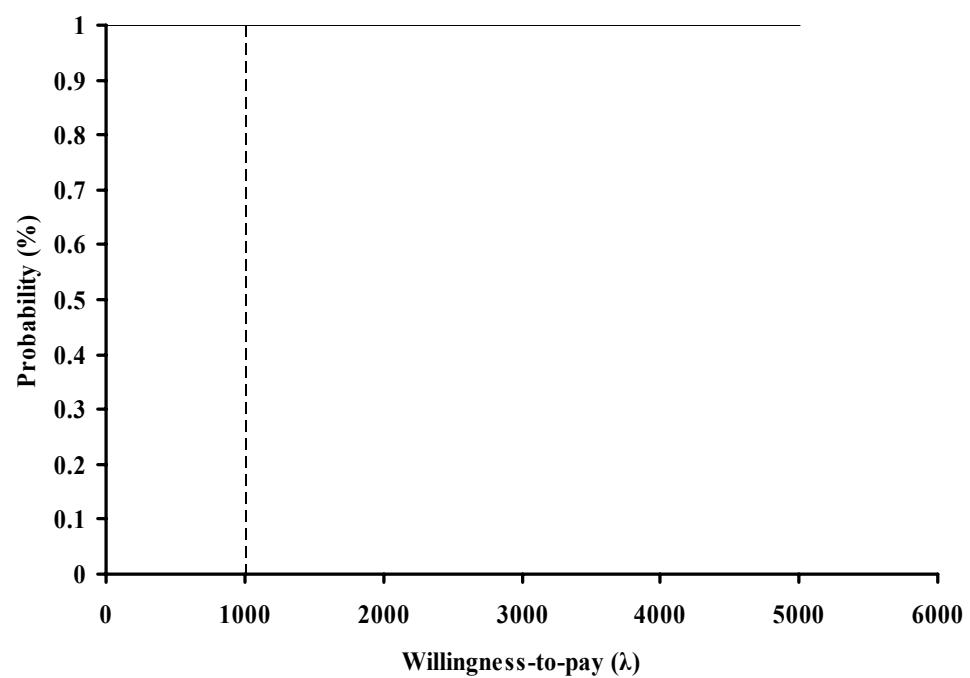


Figure 3. Cost-effectiveness acceptability curve



Appendices

Appendix 1. The main functions of Cost-Effectiveness Analyses

1. Definition of Cost Effectiveness Analyses

CEA compares the costs and outcomes of two or more strategies, when outcomes are different but measured in a single dimension.

3. Components of CEA

- Compared alternative strategies
- Costs (C)
- Outcomes/Effects (E)
- Perspective of the evaluation

4. Costs

Direct costs - the costs of recourses used by the health care sector to provide treatments (visits, drugs, overhead) and costs used to access care (out-of-pocket expenses such as for travel & accommodation)

Indirect costs - lost work time of the patient or supporting family member (productivity loss)

- wage rates (human capital method, friction cost method)

Intangible costs- costs of anxiety, uncertainly or pain caused by the treatment

Total Cost= Unit cost×Quantity

5. Incremental Cost Effectiveness Ratio= Δ Costs/ Δ Outcomes

Cost per unit of health benefit obtained from switching from one intervention to another

6. Incremental net monetary benefit (INMB):

$$b(\lambda) = \Delta e^* \lambda - \Delta c$$

- where $\Delta e^* \lambda$ = Increase in number of units of effectiveness times what we are willing to pay (WTP) for a unit of effectiveness (λ)
- the benefit of the increase in effectiveness is expressed in monetary terms

Incremental net health benefit (INHB):

$$INHB = \Delta e - \Delta c / \lambda$$

7. Discounting-

$$PV = F / (1+r)$$

PV=Present Value, F- future cost, r- time for discounting

Appendix 2. Journal form for telephone survey

ID	Name	Telephone #	Place of living	Date of stent placement/CABG	Date of contact	Result	Other

Options for “Result”:

- a. Complete
- b. Incomplete
- c. Absent at time of interview
- d. Refused to participate
- e. Absent from the country
- f. Impossible to contact
- g. Dead

Appendix 3. Medical Record sheet used in NMMC

Demographic Characteristics		
Patient's first, last name _____	1. ID# _____	
2. Date of birth ____ / ____ / ____	3. Date of intervention ____ / ____ / ____	4. Intervention type 0. <input type="checkbox"/> CABG 1. <input type="checkbox"/> PCI
Cardiac Status		
5. Stable angina	0. <input type="checkbox"/> No 1. <input type="checkbox"/> Yes	
6. Unstable angina	0. <input type="checkbox"/> No 1. <input type="checkbox"/> Yes	
7. Myocardial infarction	0. <input type="checkbox"/> No 1. <input type="checkbox"/> Yes If Yes → 0. <input type="checkbox"/> non ST elevated MI 1. <input type="checkbox"/> ST elevated MI	
7a. MI onset time	1. <input type="checkbox"/> At the time of admission 2. <input type="checkbox"/> < 3 months before intervention 3. <input type="checkbox"/> 3-6 months 4. <input type="checkbox"/> > 6 months	
8. Heart failure	0. <input type="checkbox"/> No 1. <input type="checkbox"/> Yes If Yes → NYHA class 0. <input type="checkbox"/> I 1. <input type="checkbox"/> II 3. <input type="checkbox"/> III 4. <input type="checkbox"/> IV	
9. Arrhythmia	0. <input type="checkbox"/> No 1. <input type="checkbox"/> Yes	
Risk Factors and Comorbidities		
10. Weight (kg) _____	17. Diabetes Mellitus	0. <input type="checkbox"/> No 1. <input type="checkbox"/> Yes
11. Height (sm) _____	18. Hypercholesterolemia	0. <input type="checkbox"/> No 1. <input type="checkbox"/> Yes
12. Smoking status 0. <input type="checkbox"/> No 1. <input type="checkbox"/> Yes	19. Renal dysfunction	0. <input type="checkbox"/> No 1. <input type="checkbox"/> Yes
13. Family history-CVD 0. <input type="checkbox"/> No 1. <input type="checkbox"/> Yes	20. Hypertension	0. <input type="checkbox"/> No 1. <input type="checkbox"/> Yes
14. Ejection Fraction %	21. Chronic lung disease	0. <input type="checkbox"/> No 1. <input type="checkbox"/> Yes
15. Infectious endocarditis 0. <input type="checkbox"/> No 1. <input type="checkbox"/> Yes	22. Peripheral vascular disease	0. <input type="checkbox"/> No 1. <input type="checkbox"/> Yes

16. Cerebral Vascular Disease CVA/ TIA	0. <input type="checkbox"/> No 1. <input type="checkbox"/> Yes	17a. Ejection fraction
		0. Good (≥ 50)
		1. Fair (49-30)
		2. Poor (< 30)
Prior Interventions		
23. Angiography at the time of intervention	0. <input type="checkbox"/> No 1. <input type="checkbox"/> Yes #	
24. Previous PCI	0. <input type="checkbox"/> No 1. <input type="checkbox"/> Yes	
25. Previous CABG	0. <input type="checkbox"/> No 1. <input type="checkbox"/> Yes	
26. Previous Valve Surgery	0. <input type="checkbox"/> No 1. <input type="checkbox"/> Yes	
Diseased Coronary Vessels (> 50 % Stenosis)		
27. Type of the diseased vessels (mark all that apply)	28. Number of diseased vessels	
a. <input type="checkbox"/> Left anterior descending	1. <input type="checkbox"/> Single 2. <input type="checkbox"/> Two 3. <input type="checkbox"/> Three vessel	
b. <input type="checkbox"/> Left circumflex		
c. <input type="checkbox"/> Right coronary		
29. Number of stents placed (stent patients)	30. Number of grafts (CABG patients)	
1. <input type="checkbox"/> One 2. <input type="checkbox"/> Two 3. <input type="checkbox"/> Three	1. <input type="checkbox"/> One 2. <input type="checkbox"/> Two 3. <input type="checkbox"/> Three	
31. Hospital length of stay (days)	_____	

Appendix 4. Coronary Intervention Outcome Questionnaire

A) English version

Questionnaire #	ID#
Day of the interview (day/month/year)	Start time of the interview (hours/minutes)
	End time of the interview(hours/minutes)

General health and healthy behavior

Dear _____, first I am going to ask you few questions about your general health.

Q#1.In general would you say your health is...?

1. Excellent
2. Good
3. Satisfactory
4. Fair
5. Poor

Q#2.Overall, how would you describe your heart condition now compared to before you had your heart operation/stent?

1. Much worse
2. A little worse
3. About the same
4. A little better
5. Much better

Q#3. Does your health now limit you?

1. A lot
2. A little
3. Not limit at all

Q#4. Are the results from your heart operation/stenting:

1. Worse than you expected
2. About what you expected
3. Better than you expected

Q#5. Are you currently smoking?

NO YES if yes please indicate number of cigarettes you consume in one day and the duration for whole life.

1. less than 10 cigarettes a day
2. from 10 to 20 cigarettes a day
3. from 20 cigarettes to 30 cigarettes a day
4. more than 30 cigarettes a day

years

Q#6. How often do you exercising or walking in a street?

1. At least once a day
2. At least three times a week
3. At least once a week
4. Occasionally
5. Never

Compliance with medications

Q#7. After your heart operation/stenting have you been prescribed any medication by your doctor?

0. NO

1. YES, if yes

Q#7a. Have you followed all instructions that your doctor gave you related to medication use after the intervention?

1. Yes
2. Somewhat
3. No

Q#8. Please recall the most expensive medication(s) you were prescribed after the intervention and how long did you take it.

1. _____
2. _____

Readmissions and costs

Q#9. We want to know if after your intervention at the NMMC till now you have ANY hospital admission for MI or repeat revascularization or coronary arteriography.

0. No

1. Yes → If Yes, can you please tell us about the event(s)? We understand that you may not remember the exact details about the event but we hope that you will be able to recall it as accurate as possible.

Event 1. MI 2. Repeat rev_stent(RRS) 3. Repeat Rev- CABG(RRC) 4. Coronary arteriography(CA)	Date	Hospital	Duration of hospital stay for the event (days)	Costs 'Formal' 'Informal' 'Other' 'Total' 'Don't Remember'	Formal Costs(\$ or AMD)
				F: _____ Not F: _____ Other: _____ Total: _____ D/R _____	
				F: _____ Not F: _____ Other: _____ Total: _____ D/R _____	
				F: _____ Not F: _____ Other: _____ Total: _____ D/R _____	

Total number of events (MI + RR + Death): _____
‘Formal cost’ - the money paid for the admission.
‘Informal cost’ - the cost paid to doctors
‘Total cost’ if the respondent cannot recall separate costs.
‘Other’ - costs for transportation, medication, laboratory analysis.

Working status and income

Q#10. Are you currently working?

0. NO 1. YES if yes probe Q#11a, if No probe Q#11b.

**Q#10a. During the past 4 weeks, have you had difficulty performing work as a result of your heart condition? 0. NO
1. YES**

Q#10b. Is it due to your heart condition? 0. NO 1. YES

Q#11. From the following categories which one best describes your household total monthly income in 2008?

1. < 25,000 AMD
2. 25,000 – 50,000 AMD
3. 51,000 – 100,000 AMD
4. 101,000 -250,000 AMD
5. >250,000 AMD
6. Don’t know
7. My Relatives help

Q#13. Please, specify if there is anything else you would like to tell us about your heart operation/stenting or costs that are not covered in this questionnaire?

THANK YOU FOR YOUR PARTICIPATION!

B) Armenian Version

Ծ ³ հօԱ ³ Յ ³ Սէ ³ ԱՇԻ Ա (Սն/ ³ ՍՇէ/Ի ³ հՇ)	Ծ ³ հօԱ ³ Յ ՇԻ ԾՎՄԱ _____ (Ա ³ Ս/հԱԱ») Ծ ³ հօԱ ³ Յ ³ Ի ³ նԻ Ա _____ (Ա ³ Ս/հԱԱ»)
---	---

Ընդհանուր առողջական վիճակ և առողջ վարքագիծ

Դարգելի _____, առաջին հերթին ես կիարցմեմ Ձեր ընդհանուր առողջական վիճակի մասին:

Q#1. Ինչպե՞ս կրնութագրեք Ձեր առողջական վիճակն ընդհանրապես:

- 1.Գերազանց
- 2.Լավ
- 3.Բավարար
- 4.Վատ
- 5.Շատ վատ

Q#2. Ընդհանուր առմամբ ինչպե՞ս կզնահատեք Ձեր սրտի հետ կապված առողջական վիճակը հիմա համեմատած մինչ միջամտությունը:

1. Շատ վատ
2. Մի փոքր վատ
3. Հանարյա նույնը
4. Մի փոքր ավելի լավ
5. Շատ ավելի լավ

Q#3. Արդյո՞ք Ձեր առողջական վիճակը նեղում է Ձեզ:

1. Շատ
2. Մի փոքր
3. Ընդհանրապես չի նեղում

Q#4 Զեր վիրահատումից/ստենտավորումից հետո ստացված արդյունքները

1. Զեր սպասվածից ավելի վատ էին
2. Համարյա նույն էին ինչ Դուք սպասում էիք
6. Մի փոքր ավելի լավ
7. Շատ ավելի լավ

Q#3. Արդյո՞ք Զեր առողջական վիճակը նեղում է Զեզ:

2. Շատ
2. Մի փոքր
3. Ընդհանրապես չի նեղում

Q#4 Զեր վիրահատումից/ստենտավորումից հետո ստացված արդյունքները

3. Զեր սպասվածից ավելի վատ էին
4. Համարյա նույն էին ինչ Դուք սպասում էիք
5. Զեր սպասվածից ավելի լավ էին

Q#5. Դուք ներկայումս ծխու՞մ եք :

0.Ոչ

2. բայց նախկինում ծխել եմ _____ տարի, օրական ____ գլանակ:

1.Այո , եթե այո խնդրում եմ նշեք օրական քանի գլանակ եք օգտագործում և որքան ժամանակ:

1. 10-ից քիչ
2. 10-20 գլանակ
3. 20-30 գլանակ
4. 30-ից ավել գլանակ

-----տարի

Q#6 Ի՞նչ հաճախականությամբ եք մարզվում կամ զբոսանում դուրս (փողոցում,բակում):

1. Ամենաքիչը օրական մեկ անգամ
 2. Ամենաքիչը շաբաթական երեք անգամ
 3. Ամենաքիչը շաբաթական մեկ անգամ
 4. Առիթից առիթ
 5. Երբեք

Ղեղ որայքի ընդունման հետևողականությունյան մասին:

Q#7. Զեր Վիրահատությունից/սանդուափորումից հետո Զեզ դեղորայքի նշանակումներ արվել են Զեր բժշկի կողմից:

0. Ոչ
1. Այն, եթե այն

Q#7a Դուք հետևել ե՞ք Ձեր բժշկի կողմից տրված դեղորայքին վերաբերվող բոլոր ցուցումներին վիրահատությունից/ստենտավորումից հետո:

- ## 1. Այս ինչոր չափով

Q#8. Խաղորում են մտարերեք միջամտությունից հետո Զեզ Աշակերտ ամենաքաղաքացի դեր և օգտագործման տևողությունը:

1. _____
 2. _____
 3. _____

Վերահոսպիտալացում և միջամտությունից հետո կատարված ծախսեր :

Q#9. Մենք ցանկանում ենք իմանալ արդյոք Ձեր վիրահատությունից/ ստենտավորումից հետո ունեցել եք որևէ հետադարձ այց հոսպիտալացումով Ինֆարկտի, Վերաստենտավորնան կամ Վիրահատման և Անոթային զոնդավորնան պատճառով:

- 0 Πξ□
1 Αγν□, ήτε αյη կարող ե՞ք պատմել այդ դեպքերի մասին: Մենք հասկանում ենք ,որ Դուք հնարավոր է չիշեք ամենինչ մանրակրկիտ, բայց
հուսով ենք, որ կօանար հիշել Ձեր ուժերի

1. MI 2. Repeat revascularisation- stent(RRS) 3. Repeat Revascularisation- CABG(RRC) 4. Coronary arteriography(RCAG)	Date	Hospital	Duration of hospital stay for the event (days)	Costs 'Formal' 'Informal' 'Other' 'Total' 'Don't Remember'	Formal Costs(\$ or AMD)
				F: _____ Not F: _____ Other: _____ Total: _____ D/R _____	
				F: _____ Not F: _____ Other: _____ Total: _____ D/R _____	
				F: _____ Not F: _____ Other: _____ Total: _____ D/R _____	
				F: _____ Not F: _____ Other: _____ Total: _____ D/R _____	

Total number of events (MI + RR + Death): _____

'Formal cost' - the money paid for the admission.

'Informal cost' - the cost paid to doctors

'Total cost' if the respondent cannot recall separate costs.

'Other' - costs for transportation, medication, laboratory analysis.

Աշխատանքային կարգավիճակ և եկամուտ:

Q#10. Դուք ներկայումս աշխատում ե՞ք:

0. Ոչ 1. Այո եթե այո, ապա փորձիր Q#10a, եթե ոչ ապա փորձիր Q#10b

Q#10a Անցած չորս շաբաթվա ընթացքում ունեցե՞լ եք դժվարություն գործ կատարելու ժամանակ Զեր սրտային վիճակի պատճառով:

0. Ոչ 1. Այո

Q#10b Դա Զեր հիվանդության պատճառով է՞:

0. Ոչ 1. Այո

Q#11. 2008 թվականին Զեր ընտանիքի բոլոր անդամների կողմից ունեցած միջին տարեկան եկամուտը կազմել է՝

1. ոչ ավելի, քան 25,000 դրամ
2. 25,000-50,000 դրամ
3. 51,000-100,000 դրամ
4. 101,000-250,000 դրամ
5. ավելի քան 250,000 դրամ
6. չգիտեմ
7. բարեկամներ են օգնում

Q#12. Եքն որևից քան ունեք ավելացնելու կապված այս հարցաշարի , Զեր վիրահատության/ստենտավորման կամ աժրեքների հետ խնդրեմ կարող եք ասել:

Ծնորհակալություն Զեր Մասնակցության Դամար:

Appendix 5. Consent Forms

American University Of Armenia Institutional Review Board # 1/Committee On Human Research College Of Health Sciences Subcommittee For Student Theses

CONSENT FORM (PCI patients)

Title of Research Project: Coronary Artery Bypass Grafting versus Percutaneous Coronary Intervention with Drug Eluting Stent in Armenia: Cost-Effectiveness study

Hello dear _____ (patient's name), my name is Anush Perikhanyan. I am a second year student of the Public Health faculty at the American University of Armenia

Explanation of Research Project: We are asking you to take part in a research study that compares the costs and effectiveness of available treatment options for patients with ischemic disease in Armenia: namely, drug-eluting stent and coronary artery bypass surgery. You have been contacted because based on Nork Marash Medical Center records you underwent stenting in period from 2004 to 2005. Your participation in this study will help future patients in their decision making and may have impact on the hospital policies.

I will ask you questions about your current, health, compliance with drugs and physical activity, readmissions in hospitals after the intervention and your health care expenditures. It will take approximately 15 minutes to answer the interview questions.

There is no any risk for you to enter in this study. Your participation in this research study is entirely voluntary and does not assume any benefit for you. You can refuse to participate or discontinue at any time of the survey. There is no any penalty for refusing to participate. Whether or not you are in the study will not affect your future encounters with the NMMC. You can avoid answering the questions you consider sensitive for you. The information I collect today will be kept confidentially and only aggregated data without any patient name will be published. All data will be stored in a locked cabinet. If you have any questions about the study, including the final results, I will leave our contact numbers ((374 1) 51 25 68) ask Varduhi Petrosyan). The person in charge of the study will be happy to answer your questions.

Subject's agreement

Բանավոր Համաձայնագիր (Ստենտավորված հիվանդների համար)

Պասկած զարկերակների շունտավորմը ի տարբերություն դեղորայքապատ ստենտի միջոցով Ենթամաշկային զարկերակների միջամտմանը Հայաստանի Հանրապետությունում. Արժեք և Արդյունավետություն:

Բարև Ձեզ հարգելի _____ (հիվանդի անունը): Իմ անունը Անուշ է: Ես սովորում եմ Հայաստանի Ամերիկյան Համալսարանի Հանրային Առողջապահության ֆակուլտետի երկրորդ կուրսում:

Մենք ակնկալում ենք Ձեր մասնակցությունը մեր հետազոտությանը, որը համեմատում է իշեմիկ հիվանդների համար Հայաստանում առկա բուժման միջամտությունների արժեքը և արդյունավետությունը. որոնք են «պասկած զարկերակների շունտավորումը» և «դեղորայքապատ ստենտով միջամտումը»: Դուք ընտրվել եք, որովհետև Նորք Մարաշ Բժշկական Կենտրոնի գրանցված տվյալներով Դուք ստենտավորվել եք 2004-ից 2005 տարիների ընթացքում: Ձեր մասնակցությունը այս հետազոտության մեջ կօգնի ապագայում նմանատիպ հիվանդներին կատարել ճիշտ ընտրություն, ինչպես նաև կարող է ազդել հիվանդանոցների քաղաքականության վրա:

Ես կտամ Ձեզ հարցեր Ձեր ներկա առողջական վիճակի, դեղորայքի և ֆիզիկական վարժությունների հետևողականության, միջամտությունից հետո վերադարձ այցերի և Ձեր առողջության վրա կատարված ծախսերի մասին: Հարցազրույցին պատասխաններ տալու համար Ձեզանից կպահանջվի ընդամենը 15 րոպե:

Հետազոտության մեջ Ձեր մասնակցությունը գերծ է որևէ ռիսկերից: Ձեր մասնակցությունը այս ուսումնասիրությունների մեջ բոլորովին կամավոր է, այն չի ենթադրում որևէ պարզեց: Դուք կարող եք հրաժարվել կամ ընդհատել հետազոտությունը ունը ցանկացած պահին: Այստեղ չկա ոչ մի պատիժ չնասնակցելու դեպքում: Անկախ նրանից թե Դուք կմասնակցեք այս հետազոտությանը թե ոչ, ոչինչ չի ազդի Ձեր ՆՍՐԿ ապագա այցելության վրա: Դուք կարող եք չպատասխանել այն հարցերին, որոնք կիհանարեք խիստ անձնական կամ զգայուն: Այսօրվա ստացված ինֆորմացիան կպահվի գաղտնի և միայն հավաքական/համառոտ տվյալները կիրապարակվեն առանց որևէ հիվանդի անունի: Ողջ արդյունքները կպահպեն կողղպված կարինետում:

Եթե Դուք որևէ հարց ունենաք այդ թվում նաև հետազոտության վերջնական տվյալների մասին, խնդրում ենք Ձեզ առանց մտավախության զանգահարել հետևյալ հեռախոսահամարով (374 1) 51 25 68 Վարդուհի Պետրոսյանին: Հետազոտության համար պատասխանատու անձը ուրախ կլինի պատասխանել բոլոր Ձեզ հուզող հարցերին:

Շնորհակալություն ժամանակ տրամադրելու համար:

CONSENT FORM (CABG patients)

Title of Research Project: Coronary Artery Bypass Grafting versus Percutaneous Coronary Intervention with Drug Eluting Stent in Armenia: Cost-Effectiveness study

Hello dear _____ (patient's name), my name is Anush Perikhanyan. I am a second year student of the Public Health faculty at the American University of Armenia

Explanation of Research Project: We are asking you to take part in a research study that compares the costs and effectiveness of available treatment options for patients with ischemic disease in Armenia: namely, drug-eluting stent and coronary artery bypass surgery. You have been contacted because based on Nork Marash Medical Center records you were operated in period from 2004 to 2005. Your participation in this study will help future patients in their decision making and may have impact on the hospital policies.

I will ask you questions about your current, health, compliance with drugs and physical activity, readmissions in hospitals after the intervention and your health care expenditures. It will take approximately 15 minutes to answer the interview questions.

There is no any risk for you to enter in this study. Your participation in this research study is entirely voluntary and does not assume any benefit for you. You can refuse to participate or discontinue at any time of the survey. There is no any penalty for refusing to participate. Whether or not you are in the study will not affect your future encounters with the NMMC. You can avoid answering the questions you consider sensitive for you. The information I collect today will be kept confidentially and only aggregated data without any patient name will be published. All data will be stored in a locked cabinet. If you have any questions about the study, including the final results, I will leave our contact numbers ((374 1) 51 25 68) ask Varduhi Petrosyan). The person in charge of the study will be happy to answer your questions.

Subject's agreement

Բանավոր Համաձայնագիր (Շունտավորված հիվանդների համար)

Պսակածն զարկերակների շունտավորմը ի տարբերություն դեղորայքապատ ստենտի միջոցով Ենթամաշկային զարկերակների միջամտմանը Հայաստանի Հանրապետությունում. Արժեք և Արդյունավետություն:

Բարև Ձեզ հարգելի_____ (հիվանդի անունը): Ին անունը Անուշ է: Ես սովորում եմ Հայաստանի Աներիկյան Համալսարանի Հանրային Առողջապահության ֆակուլտետի երկրորդ կուրսում:

Մենք ակնկալում ենք Ձեր մասնակցությունը մեր հետազոտությանը , որը համեմատում է իշեմիկ հիվանդների համար Հայաստանում առկա բուժման միջամտությունների արժեքը և արդյունավետությունը . որոնք են « պսակածն զարկերակների շունտավորումը» և «դեղորայքապատ ստենտով միջամտումը»: Դուք ընտրվել եք, որովհետև Նորք Մարաշ Բժշկական Կենտրոնի գրանցված տվյալներով Դուք վիրահատվել եք 2004-ից 2005 տարիների ընթացքում: Ձեր մասնակցությունը այս հետազոտության մեջ կօգնի ապագայուն ննանատիպ հիվանդներին կատարել ճիշտ ընտրություն, ինչպես նաև կարող է ազդել հիվանդանոցների քաղաքականության վրա:

Ես կտամ Ձեզ հարցեր Ձեր ներկա առողջական վիճակի, դեղորայքի և ֆիզիկական վարժությունների հետևողականության, միջամտությունից հետո վերադարձ այցերի և Ձեր առողջության վրա կատարված ծախսերի մասին: Հարցազրույցին պատասխաններ տալու համար Ձեզանից կպահանջվի ընդամենը 15 րոպե:

Հետազոտության մեջ Ձեր մասնակցությունը գերծ է որևէ ռիսկերից: Ձեր մասնակցությունը այս ուսումնասիրությունների մեջ բոլորովին կամավոր է, այն չի ենթադրում որևէ պարզեցնելու համար կարող եք հրաժարվել կամ ընդհատել հետազոտությունը ունը ցանկացած պահին: Այստեղ չկա ոչ մի պատիժ չնասնակցելու դեպքում: Անկախ նրանից թե Դուք կմասնակցեք այս հետազոտությանը թե ոչ, ոչինչ չի ազդի Ձեր ՆՍԲԿ ապագա այցելության վրա: Դուք կարող եք չպատասխանել այն հարցերին, որոնք կիամարեք խիստ անձնական կամ զգայուն: Այսօրվա ստացված ինֆորմացիան կպահվի գաղտնի և միայն հավաքական/համառոտ տվյալները կիրապարակվեն առանց որևէ հիվանդի անունի: Ողջ արդյունքները կպահվեն կողպված կարինետում:

Եթե Դուք որևէ հարց ունենաք այդ թվում նաև հետազոտության վերջնական տվյալների մասին, խնդրում ենք Ձեզ առանց մտավախության զանգահարել հետևյալ հեռախոսահամարով (374 1) 51 25 68 Վարդուիի Պետրոսյանին: Հետազոտության համար պատասխանատու անձը ուրախ կլինի պատասխանել բոլոր Ձեզ հուզող հարցերին:

Շնորհակալություն Ժամանակ տրամադրելու համար:

Appendix 6. Results of the interview

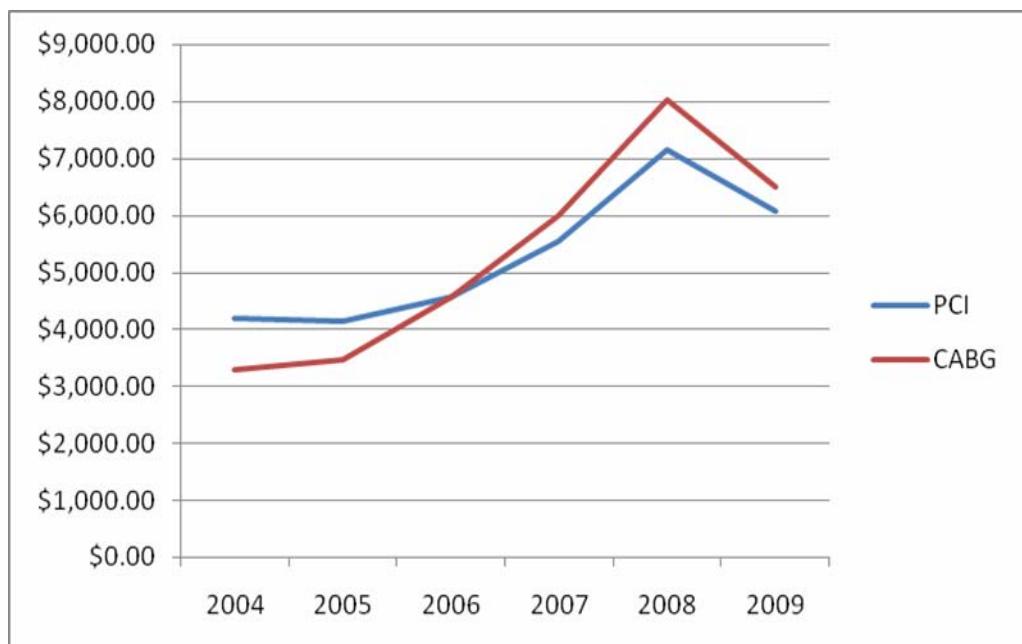
Question	Categories	PCI n=62(%)	CABG n=62(%)	P- value
<i>General Health</i>	Excellent	4 (6.56)	1(1.67)	0.2144
	Good	14(22.95)	10(16.67)	
	Satisfactory	33(54.10)	38(63.33)	
	Fair	8(13.11)	9 (15.00)	
<i>Before the intervention and now</i>	Poor	2 (3.28)	2 (3.33)	0.2105
	Much worse	2 (3.28)	1 (1.69)	
	A little worse	6 (9.84)	1 (1.69)	
	About the same	10(16.39)	10(16.95)	
	A little better	19(31.15)	22(37.29)	
	Much better	22(36.07)	25(42.37)	
	Cannot say	2 (3.28)	-	
<i>Does your health now limit you?</i>	A lot	14(22.95)	8(13.58)	0.9632
	A little	22(36.07)	32(54.24)	
	Not limit at all	25(40.98)	19(32.20)	
<i>Smoking status</i>	No	22 (36.1)	19 (31.1)	0.8371
	Yes	13(21.3)	16(26.2)	
<i>In the past</i>		26(42.6)	26(42.6)	
<i>Number of cigarettes per day</i>	<10	3 (6.3)	5 (11.4)	0.8138
	10-20	10(20.8)	8 (18.2)	
	21-30	19(39.6)	16(36.4)	
	>30	15(31.9)	15(34.1)	
<i>Smoking duration</i>	<10 years	2(4.3)	-	0.9586
	10-20 years	9(19.1)	8(18.2)	
	21-30 years	17(36.2)	22(50.0)	
	>30 years	19(40.4)	14(31.8)	
<i>Physical Activity</i>	Every day	32(52.46)	34(56.67)	0.6123
	At least three times a week	4 (6.56)	3 (5.00)	
	At least once per week	1 (1.64)	1 (1.67)	
<i>Occasionally</i>		10(16.39)	12(20.00)	
<i>Never</i>		14(22.95)	10(16.67)	

<i>Adherenc e to medicatio ns</i>	Yes	56(91.80)	52(86.67)	
	Somewhat	4(6.56)	8(13.33)	
	No	1(1.64)	0 (0)	0.9795
<i>Working status</i>	Yes	34(55.74)	32 (51.61)	0.752
<i>I lost my work due to heart condition</i>	Yes	11 (39.29)	13 (46.43)	0.4142
	1.<25.000AMD	2 (3.28)	1 (1.67)	
	2.25.000-50.000AMD			
	3.51.000- 100.000AMD	11(18.03)	7 (11.67)	0.5498
<i>Income status</i>	4.101.000- 250.000AMD	14 (22.95)	19 (31.67)	
	5.>250.000AMD	11(18.03)	10 (16.67)	
	6.Do not know	8 (13.11)	4 (6.67)	
	7.My relatives Help	9 (14.52)	11 (18.33)	
		4 (6.56)	4 (6.67)	

Appendix 7. Unit Costs for PCI and CABG

Years	Unit Costs PCI	Unit Costs CABG
2004-	- \$4,200.00	- \$3,300.00
2005-	1,900,000.00 AMD / \$4,151.28	1,900,000.00 AMD /\$3,469.1
2006-	1,900,000.00 AMD/ \$4,566.869	1,900,000.00 AMD /\$4,566.869
2007-	1,900,000.00 AMD / \$5,554.256	2,050,000.00 AMD/ \$5,992.75
2008-	2,180,000.00AMD/ \$7,145.198	2,450,000.00AMD/ \$8,030.154
2009-	2,100,000.00AMD/ \$6,079.9	2,250,000.00AMD/ \$6,514.186

Figure 4. Cost trends of PCI/DES vs CABG in NMMC from 2004 to 2009 years



Appendix 8. Multiple linear regression

Multiple linear regression analysis of number of MACE

. xi: regress numMACE interv i.vesselType i.numves diffused i.angina cholest						
i.vesselType	_IvesselTyp_1-5 (naturally coded; _IvesselTyp_1 omitted)					
i.numves	_Inumves_1-4 (naturally coded; _Inumves_1 omitted)					
i.angina	_Iangina_0-2 (naturally coded; _Iangina_0 omitted)					
<hr/>						
Source	SS	df	MS	Number of obs =	121	
				F(12, 108) =	2.17	
Model	4.14123768	12	.34510314	Prob > F =	0.0183	
Residual	17.2141342	108	.159390132	R-squared =	0.1939	
				Adj R-squared =	0.1044	
Total	21.3553719	120	.177961433	Root MSE =	.39924	
<hr/>						
numMACE	Coef.	Std. Err.	t	P> t	[95% Conf. Interval]	
interv	-.2921688	.0987218	-2.96	0.004	-.4878524	-.0964851
_IvesselTy~2	-.1077457	.1688193	-0.64	0.525	-.4423749	.2268834
_IvesselTy~3	.000637	.1389372	0.00	0.996	-.2747606	.2760346
_IvesselTy~4	.3360557	.1988965	1.69	0.094	-.0581917	.730303
_IvesselTy~5	.1858233	.1484841	1.25	0.213	-.1084979	.4801445
_Inumves_2	.174586	.1380453	1.26	0.209	-.0990438	.4482159
_Inumves_3	.041515	.1715648	0.24	0.809	-.2985561	.3815861
_Inumves_4	.2020063	.1834578	1.10	0.273	-.1616388	.5656515
diffused	.0410371	.1274726	0.32	0.748	-.2116357	.29371
_Iangina_1	-.1399794	.1569006	-0.89	0.374	-.4509836	.1710248
_Iangina_2	-.0548056	.0898938	-0.61	0.543	-.2329907	.1233795
cholest	-.0269219	.1397271	-0.19	0.848	-.3038852	.2500414
_cons	.1912611	.1121426	1.71	0.091	-.031025	.4135473

Multiple linear regression analysis of costs

. xi: regress totalC interv i.vesselType i.numves diffused i.angina cholest
i.vesselType _IvesselTyp_1-5 (naturally coded; _IvesselTyp_1 omitted)
i.numves _Inumves_1-4 (naturally coded; _Inumves_1 omitted)
i.angina _Iangina_0-2 (naturally coded; _Iangina_0 omitted)

Source	SS	df	MS	Number of obs	=	121
				F(12, 108)	=	4.24
Model	237702314	12	19808526.1	Prob > F	=	0.0000
Residual	505083275	108	4676696.99	R-squared	=	0.3200
				Adj R-squared	=	0.2445
Total	742785588	120	6189879.9	Root MSE	=	2162.6

totalC	Coef.	Std. Err.	t	P> t	[95% Conf. Interval]
interv	-1896.605	534.7513	-3.55	0.001	-2956.574
_IvesselTy~2	-470.9878	914.4523	-0.52	0.608	-2283.591
_IvesselTy~3	853.5068	752.5882	1.13	0.259	-638.2535
_IvesselTy~4	1793.563	1077.373	1.66	0.099	-341.9773
_IvesselTy~5	2182.192	804.3013	2.71	0.008	587.9273
_Inumves_2	1188.452	747.7573	1.59	0.115	-293.7325
_Inumves_3	-429.5854	929.3236	-0.46	0.645	-2271.666
_Inumves_4	-556.2369	993.7453	-0.56	0.577	-2526.012
diffused	-253.3786	690.4875	-0.37	0.714	-1622.045
_Iangina_1	-583.5698	849.8915	-0.69	0.494	-2268.202
_Iangina_2	-133.9154	486.9324	-0.28	0.784	-1099.1
cholest	390.405	756.8669	0.52	0.607	-1109.836
_cons	4751.788	607.4487	7.82	0.000	1890.646
					5955.857