Patient Satisfaction and Medication Noncompliance following Percutaneous Coronary Intervention in Armenia

(A cross-sectional study)

Master of Public Health Integrating Experience Project

Professional Publication Framework

by

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Abbreviation List

CHD - Coronary Heart Disease

WHO - World Health Organization

CABG - Coronary Artery Bypass Grafting

PCI - Percutaneous Coronary Intervention

AHA - American Heart Association

DES - Drug-Eluting Stent

Tx - Thromboxane

ADP - Adenozine DiPhosphate

AGATE - AGgrenox versus Aspirin Treatment Evaluation

NMMC - Nork-Marash Medical Center

MAS - Morisky Adherence Scale

PSQ - Patient Satisfaction Questionnaire

ROC - Receiver Operating Characteristics

AUA - American University of Armenia

MI - Myocardial Infarction

Acknowledgements

Abstract

Background: Coronary heart disease (CHD) is a major cause of morbidity and mortality throughout the world. One of the expected treatments for CHD is percutaneous coronary intervention (PCI), particularly drug-eluting stent (DES) placement. Dual antiplatelet therapy consisting of aspirin and a thienopyridine drug should be given for at least a full year for patients without major risk for bleeding. Inability of the patient to comply with the recommended therapy for DES can impact reaching therapeutic goals, often leading to a deterioration of health status. Increased risk of stent thrombosis, higher incidence of death, reinfarction, or rehospitalization are associated with medication noncompliane. Low patient satisfaction from the care received and poor health status complex the problem forming a vicious cycle with medication noncompliance.

Objective: The project evaluated the relationship between noncompliance with antiplathelet therapy (Aspirin, Clopidogrel (Plavix)), patient satisfaction, health status and medication affordability/cost in Nork-Marash Medical Center (NMMC) following DES placement.

Methods: The analytical cross-sectional telephone survey drew on a study population that consisted of a simple random sample of 375 patients aged 18 and over, who had undergone DES placement surgery at NMMC from 2006 to 2008. Among the survey items were the Morisky Adherence Scale Score (MAS), used to measure compliance (adherence) to medications, and the Short-Form Patient Satisfaction Questionnaire (PSQ-18), used to measure satisfaction with interpersonal manner, communication and general satisfaction.

Results: Mean age of the participants was 59±10 years (n=271). Most (88%) were male. The proportion of noncompliant patients was 31.0% (n=84). Only 8.1% (22 patients) reported "fair" or "poor" health status. Among the participants, 77.5% were generally satisfied with their care, 95.9% were satisfied with their caregivers' interpersonal manner, and 88.2% were satisfied with communication with their caregivers. Virtually all (97.8%) were satisfied with discharge instructions. In bivariate logistic regression analyses, age, gender, health status, smoking status and cost were associated with medication compliance (p<0.05). Compliance was not associated with satisfaction. Multiple regression analysis revealed an association between medication compliance and cost (OR=2.57, 95% CI=1.33-4.97), "very good"/ "excellent" health status (OR=2.17, 95% CI=1.18-4.01), and age (OR=1.06, 95% CI=1.03-1.09).

Conclusion: Consistent with the literature, health status, and age emerged as independent predictors of medication compliance. Patients often cited out-of-pocket costs as a contributing factor to noncompliance. Clinicians need to recognize and appropriately address these factors in following-up their patients. Further research is needed to account for time since stent placement and determining the impact of medication noncompliance on health outcomes. In addition to following the treatment guidelines, physicians should continually reinforce lifestyle advice for secondary prevention of heart attacks (e.g., smoking cessation, controlling high blood pressure).

1. Introduction

1.1 Background/ Literature Review

Coronary heart disease (CHD) is a major cause of morbidity and mortality throughout the world. According to WHO, CHD is a disease of the blood vessels supplying the heart muscle (1). CHD was the leading cause of mortality worldwide with 7.2 million deaths, accounting for 11.2% of all deaths in 2004 (2). Both surgical revascularization (coronary artery bypass grafting (CABG)) and percutaneous coronary intervention (PCI) are expected treatments for this condition (3). The acute success rate of percutaneous coronary intervention (PCI) has increased ever since its introduction, despite a widening scope of indications (4; 5; 6). Currently stents are placed in more than 50% of elective interventions, partly because they are highly effective in avoiding vessel closure (7; 8). Stenting, however, is associated with significant risk of complications, such as (sub)acute thrombosis, which occurs in 1–4% of the procedures (9; 10). Thrombosis plays a major role in acute vessel closure both after balloon angioplasty and after stenting (11).

According to the science advisory from the American Heart Association (AHA), American College of Cardiology, Society for Cardiovascular Angiography and Interventions, American College of Surgeons, and the American Dental Association with representation of the American College of Physicians, dual antiplatelet therapy consisting of aspirin and a thienopyridine drug such as clopidogrel (Plavix) or ticlopidine (Ticlid) should be given for at least a full year and perhaps even longer following certain types of stent placements for patients without major risk for bleeding (12).

The leading adverse event associated with early discontinuation of dual antiplatelet therapy is stent thrombosis, leading to an acute myocardial infarction with a 25 to 40% mortality rate. Premature discontinuation of the dual therapy is the single greatest predictor of stent thrombosis (12). Patients at even higher risk for stent thrombosis such as those with acute coronary syndromes, long stents, overlapping stents, diabetes, low ejection fraction, advanced age, and renal failure may need antiplatelet therapy for even longer, perhaps indefinitely (12). Two basic types of stents are available: bare metal and drug-eluting. Bare metal stents tend to allow growth of endothelial tissue to line the metal lumen in about 1 to 3 months. Until that occurs, the probability that the stent will thrombose is high. Once the bare metal is covered, the potential for stent thrombosis decreases and thus, antiplatelet therapy was thought to be less important after the healing period. A problem with bare metal stents is that the tissue may continue overgrow and eventually occlude the stent. To overcome that problem, drugs are imbedded in second generation stents to slow the growth of the endothelial lining, but the drugs also slow the rate of healing. These second generation drug-eluting stents (DES) therefore require longer periods of dual antiplatelet therapy, up to a year or more. They are more likely to be involved in stent thrombosis if antiplatelet therapy is interrupted during the first year (12).

According to Food and Drug Administration surveys, in 1996 only 26% of patients said that their physicians told them about their medication's side effects and how and when to take it (13). In 2004, the figure was unchanged. A similar measure of pharmacist communication actually dropped from 14% in 1996 to 6% in 2004 (13).

Medication noncompliance can be harmful for the patient and impact reaching therapeutic goals, often leading to a deterioration of health status. Patients commonly fail to take their medications

as directed, leading to unnecessary hospital admissions and even death, costing the health care system as much as $177 billion a year (13).

Approximately 50% of 1.8 billion prescription medications dispensed annually in the United States are not taken correctly by patients (14; 15). This errors lead to increased health care costs (16), morbidity and mortality (17).

In a study of 652 patients with a DES (drug-eluting stents), premature discontinuation of clopidogrel was associated with a 30-fold increased risk of stent thrombosis. Greater than 25% of patients who stopped clopidogrel in the first month suffered from stent thrombosis (12). Similarly, of patients who had DES placed after having an acute myocardial infarction and were discharged on thienopyridine therapy, 68 (13.6%) stopped therapy within 30 days. From patients who stopped thienopyridine therapy 7.5% died in the first 11 months if they stopped therapy compared with 0.7% who did not stop (12).

A recent study of patients recovering from ischemic stroke showed that more than 10% were noncompliant with aspirin (18). Noncompliance, detected by serum TX assay and on interview, occurred in 16% of the population and was associated with 4-fold higher incidence of death, reinfarction, or rehospitalization at 12 months of follow-up (19). Consistent with these findings, poorly compliant patients in the Physicians Health Study derived less benefit than compliant patients (17% versus 51% reduction in myocardial infarction compared to placebo) (20).

Noncompliance with therapy must be also assumed, when failure to respond to aspirin is assessed. Inadequate primary pharmacological effects may lead to the failure to respond to aspirin or "aspirin resistance". Depending on the population studied, the assay used, and also the

definition applied, prevalence of aspirin resistance is estimated to be between 5% and 65% (21).
Studies show, that "Clopidogrel resistance" is more common than "aspirin resistance" (22).
Although the results vary owing to differences in methods used and definitions of "resistance",
studies using ADP-induced platelet aggregation and a cut-off point at less than or equal to10%
inhibition (which is an extremely modest treatment goal) have found 5–44% "Clopidogrel
resistant" patients (23). The dosage and time since dosing are important determinants; increasing
the clopidogrel maintenance dose in "low responders" has been advocated despite lack of clinical
documentation (23; 24).

Studies suggest that the prevalence of noncompliance may even be higher. In one study about
treatment for dyslipidaemia, persistence with statins in a secondary prevention cohort (patients
with a diagnosis of myocardial infarction or angina, CABG or angioplasty, or had used nitrates
within the year before the date of the first prescription) had fallen to 71% after 6 months of
treatment and declined to 45% after 3 years. Comparable results were obtained in the primary
prevention cohort (patients without a diagnosis of cardiovascular disease or drug markers in the
year prior the date of the first prescription) where the figures were correspondingly 65% and
35% (25).

Likewise, a study about medication noncompliance in chronic kidney disease revealed, that the
prevalence of medication noncompliance was 36.9% ([95% CI], 28.6%-45.8%) (26).

Finally, a study assessing noncompliance in atherothrombotic clinical trials (27), the AGgrenox
versus Aspirin Treatment Evaluation (AGATE) trial reported at AHA (28), revealed that almost
10% among screened post-ischemic stroke patients, consciously discontinued taking their
prescribed aspirin. The study suggests that firstly, if aspirin noncompliance was so high in the

AGATE trial, most probably there are even greater risks for noncompliance in patients treated with ticlopidine and clopidogrel, due to the increased frequency of minor bleeding complications (29). Moreover, the incidence of noncompliance will be higher in case if the most effective antiplatelet agents are used, diminishing the power for the superiority of the primary vascular outcome (29).

For further complicating risk assessment the high level of noncompliance may lead to significantly underestimating the risk of bleeding events (29). Therefore, noncompliance should be recognized as a confounding factor in negative outcomes and treatment failures in clinical trials. Certain patients are discontinuing their antiplatelet medications without informing their physicians, which results in a critical rebound of platelet activation and higher vascular mortality (27). Therefore, an increased understanding of the reasons for noncompliance and lack of persistence with prescribed medication is an important step toward improving treatment effectiveness, and patient health.

Studies show, that many factors are associated with noncompliance. Such demographic variables as age (25; 30), gender (31), nationality (32), marital status (33), education (34), poor knowledge regarding prescribed medicines (26; 33), income (35), employment (34) are related to medication noncompliance.

Patient characteristics generally influencing their health such as smoking status (30), lack of low fat diet and exercise (30), poor memory (36), preexisting cardiovascular disease (33), co-morbidities; diabetes (25), hypertension (25), are also associated with noncompliance.

Factors such as lack of discharge instructions about medications or a cardiac rehabilitation referral (33), occurrence of adverse reactions (30), absence of concomitant medication (30), number of medications taken (37) and cost of medications (33) affect patients' decision to take medications as prescribed. In addition, for people living in rural areas inconveniences and challenges with travelling greater distances to pharmacies may negatively influence medication compliance (38).

From the perspective of patient satisfaction, the factors associated with noncompliance with prescribed medications are low patients satisfaction with the physician (30) and with the health care service provided (26). Satisfaction with the relationship between health care providers and patients (factors like lack of confidence in physician's ability to help the patient (38), lack of satisfaction with the concern shown by the physician (38) and lack of satisfaction with the relationships with office staff (38)) is also associated with medication noncompliance. Poor opinions of the quality of services are also related to noncompliance (26).

Lack of effective communication between the patient and health care provider often leads to decreased reliance on health care and treatment, resulting in poor disease control and noncompliance (39). Dissatisfaction with the discharge instructions is an independent correlate of noncompliance (40).

In several studies, medication noncompliance is associated with fair or poor health status (41; 42). These findings suggest that fair or poor health status of patients affects their decision to follow a prescription regimen. In addition, since there is a lack of positive results in health conditions of these patients due to poor health status, the patients just stop taking the medications or do not follow instructions because they perceive no benefit in regular treatment (31). Besides,

patient's health status and the severity of illness are also important predictors of the patient's overall satisfaction level (43; 44; 45; 46). In this situation factors like being unsatisfied with care received or with relationships with the physicians and personnel of the hospital may complex the problem, forming a vicious cycle with poor health status and medication noncompliance.

1.2 Patient Satisfaction

Medical care aims not only to improve health status but also to respond to patient needs and to ensure patients' satisfaction with care (47); thus, hospitals look for a reliable way of following-up their patients, by evaluating the patient's quality of life, and at the same time improving the standard of treatment by scoring and reflecting the patient satisfaction. As a result, patient satisfaction has become the most important direct feedback to providers on the quality of services and the relationship of services to treatment outcomes for many health care organizations (48). The assessment of satisfaction with care among hospitalized patients is increasingly recognized as a major component of quality management (49).

Various dimensions of patient satisfaction have been identified by patient satisfaction surveys aiming to improve healthcare delivery. According to the studies, quality of medical information and relationship with staff that are related to interpersonal aspects of care, and are both predictors of patient opinion on care (50). The relationship between health care providers and patients (i.e. interpersonal skills) has been reported to be the most influential factor for patient satisfaction (51; 52). As it was mentioned patient's overall satisfaction is also affected by patient's health status and the severity of illness. Besides, patient characteristics such as age and education may influence a patient's assessment of hospital performance as well (43; 51; 53). Studies have

shown that satisfaction also depends on technical quality, communication, financial aspects of care, time spent with doctor, and accessibility of care (54).

The assessment of satisfaction with care among hospitalized patients is recognized as a major component of quality management. Continuous quality improvement, comparison of hospital performances, and demands for accountability are some of the reasons that lead hospitals to measure patient satisfaction.

Different dimensions of patient satisfaction are associated with medication noncompliance in various studies. Factors like severity of illness and poor health status are related to both, medication noncompliance and patient satisfaction. Thus, looking for associations between medication noncompliance and aspects of patient satisfaction, these factors will be treated as potential confounders.

1.3 Nork-Marash Medical Center (NMMC) and the standard of care

Nork-Marash Medical Center (NMMC) provides a wide range of cardiovascular health care services to adults and children in Armenia including inpatient and outpatient treatment and follow-up of patients with congenial heart disease, coronary artery disease, and congestive heart failure. The hospital is specialized in all types of interventional cardiac procedures, such as balloon angioplasty, coronary artery revascularization with stent placement or coronary artery bypass grafting, surgical valve replacements using biological and mechanical prosthetic valves.

NMMC was established in 1993. The center has an Outpatient Clinic with three Departments (Adult Cardiology, Pediatric Cardiology and Arrhythmology), an Inpatient Clinic Surgical Department, and an Intensive Care Unit.

Approximately 400 patients undergo CABG and 300 patients undergo stent placement each year at NMMC. These patients come to NMMC from different parts of Yerevan, and from other cities and villages of the republic.

As a standard of care for PCI patients with DES, Nork-Marash Medical Center follows the guidelines for Percutaneous Coronary Intervention from AHA, prescribing clopidogrel and aspirin after DES placement (12).

The center organizes many quality assurance and improvement activities and projects, such as a multi-faceted Quality Assurance project that was launched at NMMC by AUA/CHSR in 2000 and lasted 5 years. Center's internal quality improvement is based on Continuing Quality Improvement model (55).

For internal quality evaluation purposes a survey was conducted in NMMC to assess the noncompliance with antiplatelet therapy in patients with stent placement and their satisfaction with care and with physician-patient relationship and to find an association between noncompliance and patient satisfaction. The survey aimed to yield reliable and valid measures of concepts that have both theoretical and practical significance to the planning, administration, and evaluation of health services delivery programs (56).

1.4 Aim of the Study/ Research Questions/ Objectives

The project evaluated the relationship between noncompliance with antiplatelet therapy (Aspirin, Clopidogrel (Plavix)), patient satisfaction, health status and medication affordability/cost in NMMC following stent placement.

The following research questions have been addressed:

1. What is the prevalence of medication noncompliance following stent placement in NMMC?

a. What characterizes patients who are compliant with prescribed medications compared to noncompliant patients?

b. What characterizes patient satisfaction with care, discharge instructions and with physician-patient relationship (communication, interpersonal manner) in NMMC, in patients with stent placement?

2. Does an association exist between noncompliance and patient satisfaction, health status and medication affordability/cost?

The specific objectives of the study were:

1. Estimate the prevalence of noncompliance with medications in patients with stent placement in NMMC.

2. Compare the characteristics of patients who are compliant with prescribed medications compared to the patients who are not compliant.

3. Measure patient satisfaction with care, discharge instructions and with physician-patient relationship in NMMC in patients with stent placement.

4. Evaluate the association between noncompliance and patient satisfaction, health status and medication affordability/cost.

5. Explore the main obstacles to compliance and make further recommendations to improve the situation with noncompliance with the prescribed medications in patients with stent placement and their health outcomes.

2. Methodology

2.1 Study Design

The study design is analytical cross-sectional as the aim of the study is to estimate prevalence of noncompliance and all measurements on a study subject are performed at a single point in time (57). As long as the study is not only descriptive but also aims to find an association between different variables (compliance, patient satisfaction and demographic data), it is more analytical (57).

The chosen design has the following advantages: firstly it is useful in identifying associations between variables of interest, it is cheap and simple, and data collection is performed quickly by only "one-time" interview. In addition attrition is not an issue in this case and it is ethically safe. (58). However, the study design has some disadvantages like it does not permit for distinction between cause and effect relationships in the associations, does not economize on subjects and is not useful for rare cases. The design may also be susceptible for recall bias and confounders may be unequally distributed. Finally the observed differences may be due to age/time effects or cohort effects (58).

The study was conducted by telephone interview technique. The selection of this technique is explained by the following several reasons. Patient visits to health facilities are infrequent making face-to-face interviews in the facility difficult. Moreover, telephone interviewing is safe in comparison with personal interviews at home, since there is no need for researcher to travel long distances or to enter unfamiliar houses.

However, telephone interview technique has several limitations. Firstly, some people will not be eligible because of not having phone numbers and also they can be absent from their residence. In addition, the refusal rate will likely be higher than for face-to-face interviews (57). Still, the telephone interview is the most appropriate for this study's aims and the dispersion of the target population.

2.2 Study population

The target population for this study consisted of patients who underwent drug-eluting stent (DES) placement surgery in NMMC from 2006 to 2008 year and were still alive at the time of survey. Information about the patients was extracted from NMMC cardiovascular information registry, where all the information about the patient including date of stent placement, the name of the vessel(s), the type of the stent implanted, and demographic data is provided. The telephone numbers of the patients were also extracted from these records. The inclusion and exclusion criteria were applied for those who were willing to participate.

Inclusion criteria were the following:

- Aged more than 18 years
- Residing in Armenia at the time of the survey
- Able to give consent to telephone interview.

Exclusion criteria were the following:

- Patients with CABG in the past
- Patients with stent replacement (stent placement more than one time before the call was made)

The exclusion of the patients with stent replacement is explained by the fact that additional problems with health may result in decreased reliance of treatment and negatively affect medication compliance. Besides, answers of these patients may be incorrect because of confusing prescriptions and their duration of intake after stent placement and after replacement.

As at least one year has elapsed since the patients were treated, those patients who died during this time period ("drop outs") might be different (e.g., more severe, more likely to have been noncompliant, less satisfied with their care) from those remaining in the study. Efforts were made to assess patient's health status from discharge and follow-up notes, to partly address this issue by controlling, in a limited fashion, for severity of illness.

2.3 Sampling methodology

NMMC provided a complete roster of these patients to establish the sampling frame. After checking for appropriate completeness of the list those who did not meet inclusion criteria or had any incomplete information were dropped out. Duplicates were dropped out.

The study population was chosen by simple random sampling which is known to be relatively unbiased. Simple random sampling is known to be the best way to give opportunity to each patient to be chosen. This recommended sampling strategy is the best alternative as there is a complete sampling frame available. Besides, the eligibility of the patients was not affected by not having telephone numbers, as long as all the patients had provided telephone numbers to contact.

The required information on patients for study population was collected in a Journal form (Appendix 1), that included the name of the patient, telephone, place of living, date of undertaken stent placement, date of contact and result of contact by telephone (response status).

2.4 Sample size

According to the published literature, noncompliance rates for the general population typically range from 10% to 40%. Thus, to have 80% power to detect 20% true difference in proportion of noncompliant patients between the two satisfaction groups (satisfied and unsatisfied), the following assumptions were made in estimating the required sample size:

- The prevalence of noncompliance in satisfied group was assumed 20%

- The prevalence of noncompliance in unsatisfied group was assumed 40%

- The ratio of number of people satisfied to number of people unsatisfied was assumed 4:1 (65)

- Type I error rate (α) =0.05; power (1-β)=0.80

The *statcalc* utility in EpiInfo was used (66) to calculate the required sample size of 270 Anticipating an 80% response rate (67) and a 90% eligibility rate, the sample needed to achieve a final sample of 270 was estimated as 375 (n=270/(0.8*0.9)).

2.5 Study instrument

The study instrument was formed from questions from validated questionnaires adapted for the study purposes and to the NMMC context. Particularly the survey questions elicited information about patients' demographic characteristics, medication compliance, and patient satisfaction (the key variables of interest are provided in Table 1). Questions about demographic information were adopted from Household Health Survey conducted by CHSR at AUA (59) and also from the National Survey of People with Diabetes (60). Questions regarding health status of the patients were taken from SF-36 (61) and questions regarding compliance were taken from the

Morisky Adherence Scale (MAS) to assess adherence to medications (62). MAS is a 4-item self-report scale with original binary response option (yes/no). The classification of the patients as compliant (adherent), or as noncompliant (non-adherent) depended on the proportion of binary answers (63).

For assessing patient satisfaction a validated patient satisfaction questionnaire (PSQ-18) (64) was used. The questionnaire yields separate scores for each of seven different subscales. In the questionnaire each item is accompanied by five response categories (strongly agree, agree, uncertain, disagree, strongly disagree). As long as some items are worded so that agreement reflects satisfaction with medical care, while other items are worded so that agreement reflects dissatisfaction with medical care, all the items were scored so that high scores reflect satisfaction with medical care. From the seven subscales three (General Satisfaction, Interpersonal Manner and Communication) were adapted for NMMC to evaluate the health care received by patients who underwent stent placement surgery in NMMC.

3. Ethical Considerations

The research proposal was reviewed and approved by the Institutional Review Board (IRB) within the College of Health Sciences at the AUA.

Oral consent was provided to patients in this minimal risk study evaluating the internal quality of services at NMMC. The survey did not include private or sensitive items, confidentiality was assured. Although the collected data included the information on patients' names and telephone numbers, these data were not entered into the computerized database; instead, a coded number

was used. After data entry and cleaning, the paper forms, containing respondent identifiers were destroyed. At that point anonymity was assured.

4. Data Analysis

After the interviews were completed, all available data were entered into the SPSS 11.0 for windows statistical package. Data cleaning included range checking and logical inconsistencies in responses, skip patterns, and missing data. Double entry of data from 20 randomly chosen questionnaires was performed. Data were analyzed through the Stata 10 statistical software.

Frequency analysis and descriptive analysis (Mean ± SD for continuous variables and frequencies for categorical variables) were conducted for the variables of interest and relevant socio-demographic variables (Table 1).

Prevalence of noncompliance was assessed with 95% confidence intervals (CI). Patients, who were compliant with three or more of the four MAS items (MAS score 0 or 1) were classified as compliant (adherent). Patients compliant with fewer than three of the four items (MAS score 2, 3 or 4) were classified as noncompliant (non-adherent) (63).

Mean satisfaction scores (Mean ± SD) was calculated for each of the three scales by averaging the scores of items within each scale. Each item was accompanied by five Likert-type response categories (strongly agree, agree, uncertain, disagree, strongly disagree), scored from 1 to 5 with higher scores reflecting increased satisfaction with medical care. Scores 4 and above, corresponding to "agree" and "strongly agree" were selected as the point at which to dichotomize the variable into satisfied versus unsatisfied.

A variable "smoking status" was obtained by combining two questions regarding smoking ("never", "former", "current"). The two questions were the following: "Have you ever smoked cigarettes?" and "Do you currently smoke cigarettes?". Another variable "current smoking level" regarding smoking measured the number of cigarettes smoked per day.

Health status was a subjective measure self-reported by the patient, and measured by the categories: "excellent", "very good", "good", "fair" and "poor". A new variable reduced these responses to three categories by using the middle value "good" as a referent, and combining the two responses above and the two below into a single category each.

Differences in characteristics between compliant and noncompliant patients were compared using either a standard 2-tailed t-test (for continuous variables) or a χ^2 test (for dichotomous variables).

Crude odds ratios were used to assess the relationship between each of the independent variables and the dependent variable (medication compliance).

Because of potential interaction between health status and patient satisfaction (as the healthier is the patient, the higher is the satisfaction from health care) a new variable was tested. Interaction between gender and smoking level was also taken into consideration.

Independent predictors of compliance (including patient satisfaction) were assessed using multiple logistic regression analysis. Backward stepwise technique was used for model building including all significant variables at $p > 0.05$ in univariable analysis. The final model was checked for potential confounders and effect modifiers. The model fit was assessed using the Hosmer-Lemeshow goodness-of-fit statistic and area under the Receiver Operating Curve.

5. Results

5.1 Descriptive statistics

To achieve the target of 270 respondents, a total of 375 patients were selected for interview. Ultimately 271 patients completed interviews during the data collection period (from 17 March to 08 May). Of the 104 nonrespondents, 1 (0.26%) refused to participate, 1 stopped the interview (incomplete), 7 patients were dead, 10 patients were absent from the country, and 85 patients were unavailable (wrong number, no answer, moved, etc.). The response rate was 72.3%.

Demographic and other characteristics of study participants are listed in Table 2. Their mean age was 57.51 ±9.81 years and 87.82% were male. Of the participants 98.89% were Armenian, 96.31% were married, 5.90% had an incomplete education (completed less than 10 years), 22.14% had completed schooling (10 years), 18.45% had completed professional technical education (10-13 years), 49.82% had graduated from an institute/university, and 3.69% were postgraduates. Almost 53% were currently employed; the majority of unemployed (47.23%) were retired (56.15%). These patient demographics are consistent with prior studies on CAGB patients (67) and post acute myocardial infarction (MI) patients (68).

Among the participants, 91.88% evaluated their health in general as "excellent", "very good" or "good", with only 8.12% reporting "fair" or "poor" health status. Nearly half (46.86%) were former smokers, 30.63% currently smoked, and 22.51% had never smoked. Among current smokers, the mean number of cigarettes smoked per day was 4.94 ±9.38. Among chronic conditions, 19.19% reported having diabetes diagnosed by a doctor, and 49.82% having high blood pressure. About 24.35% have had a heart attack. Virtually all (98.89%) reported that they

had received clear and understandable discharge instructions; 0.37% did not receive and 0.74% did not remember. Over three-fourths (78.23%) reported always receiving a cardiac rehabilitation referral; 18.08% reported receiving a referral some of the time, and 3.69% rarely or not at all.

5.2 Medication noncompliance

Scores for the Morisky Adherence Scale range from 0 to 4. As described above, respondents were categorized as compliant or noncompliant, using the cut-off point betweens cores 1 and 2. The proportion of compliant patients was 69.00%, and the proportion of noncompliant patients 31.00% (Table 3). The results of responses to individual MAS items are presented in Table 4. Of the 271 respondents 62 (22.87%) cited one or more reason for noncompliance, while the remaining 209 (77.13%) did not cite any reason. The most commonly cited reasons for medication noncompliance were: 19.19% (52 patients) were unable to buy medications because of the cost, 3.69% (n=10) complained of absence of prescribed medication in the available drug-stores), 1.48% (n=4) patients reported travelling distance to procure the medicine as a problem, 1.11% (n=3) had forgotten to take medications because of poor memory, 0.74 % (n=2) perceived that medicines did not help. Interestingly, no one mentioned side effects as a reason for medication noncompliance.

5.3 Patient Satisfaction

As expected, scores for three individual aspects of satisfaction showed that the population was skewed toward high satisfaction (Figure 1). This finding confirmed the primary assumption underlying the cut-off point between 3.5 and 4.0 for dichotomizing satisfaction. Dichotomization

(Table 5) resulted in 77.5% (95% CI 72.5 - 82.5) being "generally satisfied", 95.9% (95% CI 93.6 – 98.3) being satisfied with "interpersonal manner", and 88.2% (95% CI 84.3 – 92.1) were satisfied with "communication". Virtually all (97.8%, 95% CI 96.0 – 99.5) were satisfied with discharge instructions.

5.4 Standard 2-tailed t-tests and χ^2 tests

Compliant patients were significantly more likely to be older, mean 58.94 years versus 54.32 years, p = 0.000 (Table 6). Women were more likely than men to be compliant with medication regimens: 15.51 % versus 4.76%, p = 0.012. Compliant patients were more likely to be "never smokers" (26.74% versus 13.09%, p= 0.045) and currently smoke fewer cigarettes (4.29 versus 6.40, p= 0.043). Compliant and noncompliant patients significantly differed in health status: compliant patients were more likely to have "good" (42.78% versus 26.19%) health status. Patients not having difficulties with cost of medications were more likely to be compliant: 85.03% versus 71.43%, p = 0.009. Surprisingly, compliance was not associated with satisfaction, neither by the aggregate measure of satisfaction or for any of its constituent domains (Table 6).

5.5 Bivariate logistic regression

Table 7 summarizes the bivariate logistic regression analyses (crude odds ratios). Factors, such as age, gender, health status, smoking status and cost were associated with medication compliance. No association was found between compliance and any aspects of patient satisfaction (Table 7). Older patients are more compliant. The odds of being compliant with prescribed medications increases by 5% with each year of patient age (OR=1.05, 95%CI 1.02 – 1.08, p=0.000). Women are 3.67 times (95%CI 1.25 – 10.80, p=0.018) more likely to be

compliant than men. Patients with "very good" /"excellent" health status were2.05 times (95%CI 1.15 – 3.66, p=0.015) more likely to be compliant compared to patients with "good" health status. The odds of being compliant are 2.27 times greater (95% CI 1.22 – 4.22, p=0.010) among the patients for whom the cost for buying medications is not a problem. Current smokers were by 60% less likely (OR=0.40, 95%CI 0.18– 0.90, p=0.028) to be compliant compared to never smokers, and former smokers were by 59% less likely (OR=0.41, 95%CI 0.20 – 0.88, p= 0.021) to be noncompliant, compared to never smokers.

5.6 Multiple logistic regressions

Multiple logistic regression was then used to build model, that best fits the empirical data (Table 8). Potential interactions between health status and patient satisfaction (as the healthier is the patient, the higher is the satisfaction from health care) were tested. No significant interaction was found. Interaction between gender and smoking level was statistically significant (OR=1.35, 95% CI 1.03-1.78, p=0.031). All covariates identified as statistically significant (p<0.05) in the bivariate analysis (age, gender, health status, smoking status and cost) were included in a multiple logistic regression analysis. Gender and smoking status were no longer significant in the model. The final model was defined by using backward stepwise technique. The interaction term between gender and smoking level was not used in the final model, based on the results of collinearity analyses. The final model is presented in Table 8.

Multiple regression analysis revealed that cost, health status and age were the independent predictors of medication compliance. After adjusting for health status and age, the odds of being compliant was 2.57 times greater (95% CI 1.33 – 4.97) among the patients for whom the cost for buying medications is not a problem. Similarly, the odds of being compliant with prescribed

medications increased by 6% for each year of age (OR=1.06, 95%CI 1.03 – 1.09), and by 2.17 times (95% CI 1.18-4.01) for patients with "very good"/ "excellent" health status. The Hosmer-Lemeshow goodness-of-fit statistic (p=0.15) indicated that this model was a reasonable fit. Also the final model confirmed good discrimination, since the area under the Receiver Operating Characteristics (ROC) curve was 0.702. The area under the ROC curve that ranges from zero to one presents a measure of the model's ability to discriminate between those subjects who experience the outcome of interest versus those who do not (69).

A summary of these findings by research question follows:

1. The prevalence of noncompliance following stent placement was 31 %.

a. The patients in compliant and noncompliant groups significantly differed by age, gender, health status, smoking status and medication affordability/cost.

b. Patients' general satisfaction was 77.49%, satisfaction with interpersonal manners was 95.94%, satisfaction with communication was 88.19% and satisfaction with discharge instructions was 97.79%.

2. Medication compliance was not associated with patient satisfaction. In multivariate analysis medication compliance was associated with medication affordability/cost, age and health status ("very good"/"excellent" versus "good").

6. Discussion

This study estimated the prevalence of noncompliance with medications in patients with stent placement in NMMC. Only 69% of the patients were compliant. According to the published

literature, noncompliance rates for the general population generally range from 10% to 40%, and up to 65% for conditions requiring long-term compliance (19; 25; 26; 28). Particularly, according to the results of the study assessing noncompliance in atherothrombotic clinical trials (27; 28), almost 10% among screened post-ischemic stroke patients, discontinued taking their prescribed aspirin. The abovementioned study suggests that there are even greater risks for noncompliance in patients treated with ticlopidine and clopidogrel. In the current study assessing medication noncompliance with aspirin and clopidogrel, the findings are consistent with the published literature. Adherence to medications was also assessed in patients after Coronary Artery Bypass Graft (CABG) surgery in NMMC in 2007. Almost 39% were compliant (e. g., 61% noncompliant) with prescribed medications by MAS scale (67). The observed differences in the medication compliance may be due to the study populations (PCI-patients versus CABG-patients). Patients undergoing CABG surgery do not rely on medications as much as PCI patients, making less emphasized the role of medication compliance in their health outcomes. Before implanting a drug-eluting stent (DES), however, an interventional cardiologist discusses with a PCI-patient the need for and the duration of the antiplatelet therapy to confirm the patient's willingness to comply, also increasing the likelihood of compliance. In addition, medication compliance for the PCI and CABG studies involved different drug categories, with different regimens and potential side-effects that could yield different rates of compliance. Surprisingly, in post acute MI patients (68) only 25% were adherent to physicians' instructions, about 54% were fairly adherent, and about 22% were poorly adherent. The findings imply that for the patients with CHD the rates for medication compliance and adherence to physical activity are inconsistent, suggesting that the patients underestimate the role of physical activity in their health outcomes.

The study also measured patient satisfaction with care, discharge instructions, and the physician-patient relationship in NMMC in patients with stent placement. For this purpose general satisfaction, satisfaction with communication, satisfaction with interpersonal manner and satisfaction with discharge instructions were measured. All these aspects of satisfaction were rated highly, which is not surprising: according to the study performed in the Inpatient Clinic in NMMC in 2003, 96% of patients were satisfied by nursing and 92% by doctor care at Outpatient Clinic (65). According to another study conducted in NMMC, relating lost to follow-up of patients at the Outpatient Clinic, in the group of patients remaining in the follow-up 94.5% were satisfied with services and in the group of patients lost to follow-up 89.7% were satisfied(65).

Overall, satisfaction was quite skewed to better results. Such high satisfaction levels could underestimate the proposed association between medication noncompliance and patient satisfaction. This fact may explain the finding of no statistically significant association between compliance and different aspects of patient satisfaction, which is inconsistent with the published literature. In summary, study patients who were compliant with their prescribed medications differed significantly from noncompliant patients by age, gender, health status, smoking status, and medication affordability/cost. All these findings are supported by the published literature.

An association was found between medication noncompliance and medication affordability/cost. The finding was supported by literature and also by a prior study conducted at NMMC (67).

Older patients were more likely to be compliant, consistent with the literature (25; 30) and with the findings of the study on post acute MI patients (68). Health status was associated to medication compliance as well. Patients with "very good"/"excellent" health status were significantly more likely to be compliant, than patients with "good" health status, but, contrary

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to the literature (41; 42), "fair"/"poor" health status patients were not. This null finding might be explained by only a small fraction of the patients (about 8%) that reported "fair" or "poor" health status, thus yielding unstable parameter estimates given the size of the study population.

7. Study limitations

The study population was chosen by simple random sampling, strengthening the internal validity of the findings. Inclusion and exclusion criteria were consistent with previous studies and maximized the generalizability of the findings. Still, the study design and environment imposed several limitations. One study limitation was that time after stent placement was not accounted for, providing different amounts of time (one to two years) over which to recall and to become noncompliant.

Stent replacement was used as an exclusion criterion. This choice could preferentially exclude patients who were noncompliant in the past or were otherwise more likely to be noncompliant in the future. Only 5 such patents were excluded, limiting the effect of any such bias.

By excluding deceased patients, differential mortality among noncompliant cases could underreport the association. Only 7 patients were excluded due to death. While the causes of death were not available; a review of their medical histories did not reveal any consistent deviation from a typical patient profile in terms of health status, disease severity, co-morbidities, etc.

Another limitation is using self-reported information on medication compliance, which could be subject to reporting bias. Patients could overestimate their drug-taking behaviors by answering the desired options for the questions. Likewise, patients' health status is also a self-reported

measure. While a known and reliable indicator, it can deviate from objective measures of health status. Any such bias would likely result in findings closer to the null.

8. Conclusion and recommendations

Medication compliance following percutaneous coronary intervention (PCI) was 69%. The independent predictors of medication compliance were cost, health status and age. These findings are consistent with previous research. Interestingly, patient satisfaction was not associated with medication compliance. The generally high satisfaction level among all patients at NMMC might explain the null finding. Younger patients with "fair" or "poor" perceived health status and for whom the cost of buying the prescribed medications represents a problem, are more at-risk for noncompliance. NMMC should target these groups with future quality assurance activities that address medication noncompliance and ensuring better health outcomes.

Taking into consideration the mentioned limitations, further study that takes into account time period since stent placement should be conducted. Likewise, further study is needed to assess the impact of medication noncompliance on health outcomes. A qualitative study could provide useful in more fully identifying the main obstacles to medication noncompliance as well as opportunities to increase compliance.

A known obstacle to medication compliance was medication affordability/cost (67). To improve the situation with noncompliance and, thus, further outcomes of treatment, the government, the pharmaceutical industry, and health system advocates should implement efforts to reduce the economic burden on patients. In addition to following treatment guidelines, physicians should

continually reinforce lifestyle advice for secondary prevention of heart attacks (e.g., smoking cessation, controlling high blood pressure).

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Tables

Table1. Dependant and Independent Study Variables

Variable definition	Type	Levels of measurement
Dependant (outcome) variable		
<u>Medication noncompliance</u> Do you ever forget to take your medications?	Binary	Measured as: 0=no 1=yes
<u>Medication noncompliance</u> Are you careless at times about taking your medications?	Binary	0=no 1=yes
<u>Medication noncompliance</u> When you feel better, do you sometimes stop taking your medications?	Binary	0=no 1=yes
<u>Medication noncompliance</u> Sometimes if you feel worse when you take your medications, do you stop taking them?	Binary	0=no 1=yes
<u>Morisky Score</u>	Binary	0=noncompliant (2+) 1=compliant (0-1)
Independent variables		
Satisfaction with care received	Numerical *(Binary*)*	Measured as continuous variable: sum of scores of items within each scale
Satisfaction with doctor (interpersonal skills)	Numerical *(Binary*)*	Measured as continuous variable: sum of scores of items within each scale
Satisfaction with doctor (communication)	Numerical *(Binary*)*	Measured as continuous variable: sum of scores of items within each scale
<u>Satisfaction</u>	Binary	0=unsatisfied (mean score 1.0-3.5) 1=satisfied (mean score 4.0-5.0)
Satisfaction with discharge instructions (Did you know enough about when and how much medication to take?)	Nominal	1. Yes 2. No, I would like to know a little bit more 3. No, I would like to know a lot more 4. I didn't take any medication

Variable definition	Type	Levels of measurement
Satisfaction with discharge instructions	Binary	0=unsatisfied (for #2,3,4 options) 1=satisfied (for #1 option)
Health status	Ordinal	1=excellent, 2=very good, 3=good, 4=fair, 5=poor
Discharge instructions Did you get a clear and understandable explanation about how to take the prescribed medicine?	Nominal	1=yes 2=no 3= don't know/remember
Cardiac rehabilitation referral Thinking about the time, when you received care for cardiac rehabilitation, did you agree when your next appointment would be?	Nominal	1=Rarely or not at all 2=Some of the time 3=Almost always
Medication affordability/Cost What was the reason for not following the prescription?	Binary	1=yes 2=no
Absence of prescribed medication What was the reason for not following the prescription?	Binary	1=yes 2=no
Distance travelling What was the reason for not following the prescription?	Binary	1=yes 2=no
Adverse reactions What was the reason for not following the prescription?	Binary	1=yes 2=no
The medicines do not help (Perceive no benefit) What was the reason for not following the prescription?	Binary	1=yes 2=no
Poor memory What was the reason for not following the prescription?	Binary	1=yes 2=no
Smoking status Have you ever smoked cigarettes?	Binary	1=yes 2=no
Smoking status (Current smoker) Do you currently smoke cigarettes?	Binary	1=yes 2=no
Smoking level How many cigarettes per day do you smoke?	Numerical	Measured as continuous variable: ------# of cigarettes
Smoking Status (Q11+Q12)	Ordinal	1. Never 2. Current 3. Former smoker

Variable definition	Type	Levels of measurement
Diabetes Has a doctor ever told you that you have any of the following health problems or conditions?	Binary	1=yes 2=no
Hypertension Has a doctor ever told you that you have any of the following health problems or conditions?	Binary	1=yes 2=no
Heart attack Has a doctor ever told you that you have any of the following health problems or conditions?	Binary	1=yes 2=no
Age	Numerical	Measured as continuous variable: --------Year
Gender	Binary	1=male 2=female
Nationality	Nominal	1=Armenian,2=Russian 3=Yesidi, 4=Other
Marital status	Nominal	1=married, 2=single, 3=divorced,4=widowed
Education The highest level of education that you have completed:	Ordinal	1=School (less than 10 years), 2=School (10 years), 3=Professional technical education (10-13 years),4=Institute/University Postgraduate
Employment Are you currently employed?	Binary	1=yes 2=no
Employment Which of the following best describes your situation?	Nominal	1=Unemployed, looking for work, 2=Unemployed, not looking for work, 3=Can't work due to (permanent) disability, 4=Can't work due to inability to find/afford child care, 5=Student/ attending school, 6=Homemaker, 7=Retired, 8=Self-employed,9=Farmer, 10=Other

Variable definition	Type	Levels of measurement
<u>Income</u> Last month, the approximate amount of household income spent by all of your household members was:	Ordinal	1=Less than 25,000 drams, 2=From 25,000 - 50,000 drams, 3=From 51,000 - 100,000 drams, 4=From 101,000 - 250,000 drams, 5=Above 250,000drams 6=Don't know

* Variables were measured as continuous, but later were converted into binary variables (1=satisfied, 0=unsatisfied)

Table 2. Participant demographic and health characteristics

Variable name	Result (n, %)	
Age (mean±SD)	57.51 ±	9.81
Gender		
Male	238	(87.82)
Female	33	(12.18)
Nationality		
Armenian	268	(98.89)
Russian	3	(1.11)
Education		
School (< 10 years)	16	(5.90)
School (10 years)	60	(22.14)
Prof. technical education (10-13)	50	(18.45)
Institute/university	135	(49.82)
Postgraduate	10	(3.69)
Marital status		
Married	261	(96.31)
Single	3	(1.11)
Divorced	1	(0.37)
Widowed	6	(2.21)
Employment		
Employed	143	(52.77)
Unemployed	128	(47.23)
Unemployed,		
Unemployed, looking for work	9	(6.92)
Unemployed, not looking for work	18	(13.85)
Permanently disabled	14	(10.77)
Homemaker	11	(8.46)
Retired	73	(56.15)
Self-employed	2	(1.54)
Farmer	3	(2.31)
Household income (last month)		
Less than 25,000 drams	22	(8.12)
From 25,000 - 50,000 drams	56	(20.66)
From 51,000 - 100,000 drams	74	(27.31)
From 101,000 - 250,000 drams	62	(22.88)
Above 250,000drams	41	(15.13)
Don't know	16	(5.90)
Health status		
Excellent	17	(6.27)
Very good	85	(31.37)
Good	147	(54.24)
Fair	21	(7.75)
Poor	1	1 (0.37)

Smoking status		
Never	61	(22.51)
Former	127	(46.86)
Current	83	(30.63)
Current smoking level (cigarettes per day)		
	4.94	± 9.38
Diabetes		
Yes	52	(19.19)
No	219	(80.81)
Hypertension		
Yes	135	(49.82)
No	136	(50.18)
Heart attack		
Yes	66	(24.35)
No	205	(75.65)
Discharge instructions		
Yes	268	(98.89)
No	1	(0.37)
Don't know/remember	2	(0.74)
Cardiac rehabilitation referral		
Rarely or not at all	10	(3.69)
Some of the time	49	(18.08)
Almost always	212	(78.23)

Table 3. Participants' Medication Adherence Scale (MAS) score

Medication Adherence Scale (MAS) score*	Result (n, %)	Cumulative percent. (%)
0	118 (43.54)	(43.54)
1	69 (25.46)	(69.00)
2	53 (19.56)	(88.56)
3	26 (9.59)	(98.15)
4	5 (1.85)	(100.00)

*Participants with the MAS score 0 or 1 were defined as "compliant", and with the score 2 or 3 or 4 as "noncompliant"

Table 4. Medication Adherence Scale (MAS) Items

Item	Result (n, %)
Forgot to take medication	104 (38.38)
Careless about taking medication	95 (35.06)
When feeling better, stopped taking medicine	58 (21.40)
When feeling worse, stopped taking medicine	16 (5.90)

Table 5. Participants' satisfaction with constituent domains

Variable name	Result (n, %)	
General Satisfaction		
Satisfied	210	(77.49)
Unsatisfied	61	(22.51)
Satisfaction with Interpersonal Manners		
Satisfied	260	(95.94)
Unsatisfied	11	(4.06)
Satisfaction with Communication		
Satisfied	239	(88.19)
Unsatisfied	32	(11.81)
Satisfaction with Discharge Instructions		
Satisfied	265	(97.79)
Unsatisfied	6	(2.21)

Table 6. Results of Standard 2-tailed t-tests and χ^2 tests

Variable name	Compliant (n, %)		Noncompliant (n, %)		p-value
Age (mean ± SD)	58.94 ± 9.71		54.32 ± 9.31		0.000
Gender					0.012
Male	158	(84.49)	80	(95.24)	
Female	29	(15.51)	4	(4.76)	
Nationality					0.243
Armenian	184	(98.39)	84	(100.00)	
Russian	3	(1.61)	0	(0.00)	
Education					0.698
School (< 10 years)	13	(6.95)	3	(3.57)	
School (10 years)	39	(20.85)	21	(25.00)	
Prof. technical education (10-13)	35	(18.72)	15	(17.85)	
Institute/university	92	(49.19)	43	(51.19)	
Postgraduate	8	(4.27)	2	(2.38)	
Marital status					0.096
Married	178	(95.18)	83	(98.81)	
Single	3	(1.60)	0	(0.00)	
Divorced	0	(0.00)	1	(1.19)	
Widowed	6	(3.21)	0	(0.00)	
Employment					0.219
Employed	94	(50.26)	49	(58.33)	
Unemployed	93	(49.74)	35	(41.67)	
Household income					0.284
Less than 25,000 drams	15	(8.04)	7	(8.33)	
From 25,000 - 50,000	37	(19.78)	19	(22.62)	
From 51,000 - 100,000	46	(24.59)	28	(33.33)	
From 101,000 - 250,000	50	(26.74)	12	(14.28)	
above 250,000drams	27	(14.44)	14	(16.67)	
Don't know	12	(6.42)	4	(4.76)	
Health status (categorical)					0.030
Very Good/ Excellent	80	(42.78)	22	(26.19)	
Good	94	(50.27)	53	(63.09)	
Fair/Poor	13	(6.95)	9	(10.71)	
Smoking status					0.045
Never	50	(26.74)	11	(13.09)	
Former	83	(44.38)	44	(52.38)	
Current	54	(28.87)	29	(34.52)	
Current smoking level (mean ± SD) (cigarettes per day)	4.29 ± 8.58		6.40 ± 10.88		0.043
Diabetes					0.769
Yes	35	(18.72)	17	(20.24)	
No	152	(81.28)	67	(79.76)	

Variable name	Compliant (n, %)		Noncompliant (n, %)		p-value
Hypertension					0.455
Yes	96	(51.33)	39	(46.43)	
No	91	(48.66)	45	(53.57)	
Heart attack					0.437
Yes	43	(22.99)	23	(27.4)	
No	144	(77.01)	61	(72.6)	
Discharge instructions					0.085
Yes	186	(99.46)	82	(97.62)	
No	1	(0.54)	0	(0.00)	
Don't know/remember	0	(0.00)	2	(2.38)	
Cardiac rehabilitation referral					0.324
Rarely or not at all					
Some of the time	6	(3.21)	4	(4.76)	
Almost always	30	(16.04)	19	(22.62)	
	151	(80.75)	61	(72.62)	
Medication affordability/Cost					0.009
Yes					
No	28	(14.97)	24	(28.57)	
	159	(85.03)	60	(71.43)	
Absence of prescribed medication					0.444
Yes					
No	8	(4.28)	2	(2.38)	
	179	(95.72)	82	(97.62)	
Distance travelling					0.177
Yes		4 (2.14)	0	(0.00)	
No	183	(97.86)	84	(100.00)	
Poor memory					
Yes	0	(0.00)	0	(0.00)	
No	187	(100.00)	84	(100.00)	
Medications do not help					0.179
Yes	1	(0.53)	2	(2.38)	
No	186	(99.46)	82	(97.62)	
Adverse effects					0.560
Yes	1	(0.53)	1	(1.19)	
No	186	(99.46)	83	(98.81)	
General Satisfaction					0.977
Satisfied	145	(77.54)	65	(77.38)	
Unsatisfied	42	(22.46)	19	(22.62)	
Satisfaction with Interpersonal Manners					0.348
Satisfied	178	(95.18)	82	(97.62)	
Unsatisfied	9	(4.82)	2	(2.38)	
Satisfaction with Communication					0.210
Satisfied	168	(89.84)	71	(84.52)	
Unsatisfied	19	(10.16)	13	(15.48)	

Variable name	Compliant (n, %)		Noncompliant (n, %)		p-value
Satisfaction with Discharge Instructions					0.900
Satisfied	183	(97.86)	82	(97.62)	
Unsatisfied	4	(2.14)	2	(2.38)	

Table 7. Results of Bivariate Logistic Regression Analyses (Crude Odds Ratios)

Variable name	Odds Ratio	95% CI			p-value
Age	1.05	1.02	-	1.08	0.000
Gender	3.67	1.25	-	10.81	0.018
Health status (categorical)					
Very Good /Excellent	2.05	1.15	-	3.66	0.015
Good	1.00				
Fair/Poor	0.81	0.33		2.03	0.660
Smoking status					
Never	1.00				
Former	0.41	0.20	-	0.88	0.021
Current	0.40	0.18	-	0.90	0.028
Current smoking level (cigarettes per day)	0.97	0.95	-	1.00	0.090
Diabetes	1.10	0.57	-	2.10	0.769
Hypertension	0.82	0.49	-	1.37	0.455
Heart attack	1.26	0.70	-	2.27	0.437
Discharge instructions	0.28	0.05	-	1.61	0.154
Cardiac rehabilitation referral	1.42	0.88	-	2.29	0.154
Medication affordability/Cost	2.27	1.22	-	4.22	0.010
Absence of prescribed medication	0.54	0.11	-	2.63	0.450
Medications do not help	4.53	0.41	-	50.74	0.220
Adverse effects	2.24	0.14	-	36.26	0.570
General Satisfaction	1.01	0.54	-	1.87	0.977
Satisfaction with Interpersonal Manners	0.48	0.10	-	2.28	0.358
Satisfaction with Communication	1.62	0.76	-	3.45	0.213
Satisfaction with Discharge Instructions	1.11	0.20	-	6.21	0.900

Table 8. Results of Multiple Logistic Regression Analyses: Adjusted Effect of Independent Variables on Medication Compliance

Variable name	Odds Ratio	95 % CI	p-value
Cost			
Yes	1.00	referent	
No	2.57	1.33-4.97	0.005
Health status			
Very Good /Excellent	2.17	1.18-4.01	0.013
Good	1.00	referent	
Fair/Poor	0.87	0.34-2.23	0.783
Age	1.06	1.03-1.09	0.000

Figures

Figure 1. Distribution of Scores of Domains of Satisfaction
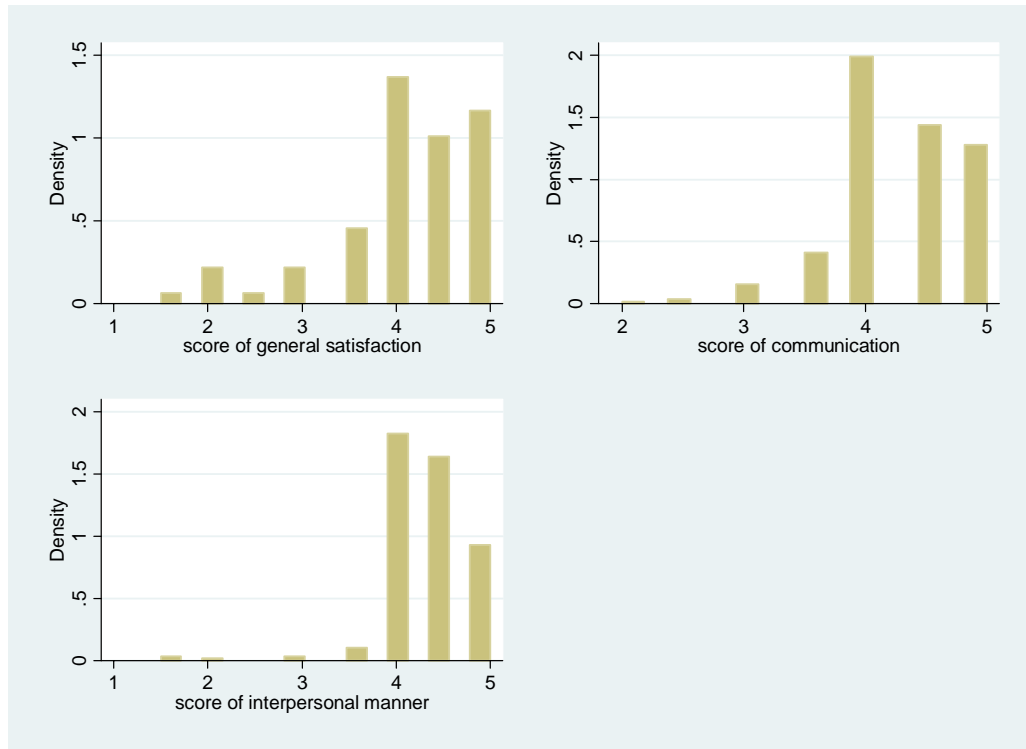
Appendix 1. Journal form

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

Options for "Result"

1. Complete
2. Incomplete
3. Refused to participate
4. Absent at time of interview
5. Absent from the country
6. Impossible to contact

Appendix 2. Questionnaire (English & Armenian)
Questionnaire

ID_____

Date of the interview _____ (Day/Month/Year)

Start time of the interview_____ (Hour/Minute)

End time of the interview _____ (Hour/Minute)

The answer should be marked by circling the number corresponding to the option or filling the blanks.

A. Demographic
Please, indicate your:

(Circle one)

1. Age: _____

2. Gender:

    1. Male
    2. Female

B. Discharge information
After you undergo stent placement,

(Circle one)

3. Did your doctor prescribed you medicines?

    1. Yes
    2. No   *(Go to Q.5)*
    88. Don't know/don't remember   *(Go to Q.5)*

4. Did you get a clear and understandable explanation about how to take the prescribed medicine (time of day and dosage)?

    1. Yes
    2. No
    88. Don't know/remember

5. Thinking about the time, when you received care for cardiac rehabilitation, did you agree when your next appointment would be?

1. Rarely or not at all
2. Some of the time
3. Almost always

6. Please list the **PRESCRIPTION** medications you have taken.

    1. Aspirin_____

    2. Plavix_____

    3. Other (specify)_____

C. Patient Satisfaction

7. Did you know enough about when and how much medication to take?

(Circle one)

1. Yes
2. No, I would like to know a little bit more
3. No, I would like to know a lot more
4. I didn't take any medication

8. How strongly do you **AGREE** or **DISAGREE** with each of the following statements?

(Circle one on each line)

	Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
A. General Satisfaction					
1. The medical care I have been receiving is just about perfect	1	2	3	4	5
2. I am dissatisfied with some things about the medical care I receive	1	2	3	4	5

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B. Interpersonal Manner					
3. Doctors act too businesslike and impersonal toward me	1	2	3	4	5
4. My doctor treat me in a very friendly and courteous manner	1	2	3	4	5
C. Communication					
5. Doctors are good about explaining the reason for medical tests	1	2	3	4	5
6. Doctors sometimes ignore what I tell them	1	2	3	4	5

D. Health status/ Health Behavior

(Circle one)

9. In general, would you say your health is:

1. Excellent
2. Very good
3. Good
4. Fair
5. Poor

10. Compared to one year ago how would you rate your health in general now?

1. Much better now than one year ago
2. Somewhat better now than one year ago

3. About the same as one year ago
4. Somewhat worse now than one year ago
5. Much worse now than one year ago

11. Have you ever smoked cigarettes?

1. Yes
2. No *(Go to Q.14)*

12. Do you currently smoke cigarettes?

1. Yes
2. No *(Go to Q.14)*

13. How many cigarettes per day do you smoke? _____ cigarettes

14. Has a doctor ever told you that you have any of the following health problems or conditions?

(Circle all that apply)

1. Diabetes
2. High blood pressure
3. Heart attack
4. Other *(describe)* _____

E. Medication Compliance

Thinking about the medications PRESCRIBED to you by your doctor(s), please answer the following questions:

(Circle one)

15. Do you ever forget to take your medications?

1. Yes
2. No

16. Are you careless at times about taking your medications?

1. Yes
2. No

17. When you feel better, do you sometimes stop taking your medications?

1. Yes
2. No

18. Sometimes if you feel worse when you take your medications, do you stop taking them?

   1. Yes
   2. No

19. What was the reason for not following the prescription?

(Circle all that apply)

   1. Was unable to buy medicine(s) because of cost
   2. Was unable to get medicine(s) because of absence of concomitant medications
   3. Was unable to get medicine(s) because of distance travelling
   4. Side effects/fear of side effects
   5. Forgot to take medicine(s)
   6. The medicines do not help
   7. Other *(describe)* _____

F. Socio-Demographic
Please, indicate your:

(Circle one)

20. Nationality:

   1. Armenian
   2. Russian
   3. Yesidi
   4. Other *(describe)* _____

21. Marital status

   1. Married
   2. Single
   3. Divorced
   4. Widowed

22. The highest level of education that you have completed:

   1. School (less than 10 years)
   2. School (10 years)
   3. Professional technical education (10-13 years)
   4. Institute/University
   5. Postgraduate

23. Are you currently employed?

  1. Yes *(Go to Q25)*
  2. No

24. Which of the following best describes your situation?

  1. Unemployed, looking for work
  2. Unemployed, not looking for work
  3. Can't work due to (permanent) disability
  4. Can't work due to inability to find/afford child care
  5. Student/attending school
  6. Homemaker
  7. Retired
  8. Self-employed
  9. Farmer
  10. Other _____

25. Last month, the approximate amount of household income spent by all of your household

members was:

  1. Less than 25,000 drams
  2. From 25,000 - 50,000 drams
  3. From 51,000 - 100,000 drams
  4. From 101,000 - 250,000 drams
  5. Above 250,000drams
  88. Don't know

Հարցաթերթիկ

Տարբերակման համարը _____

Հարցման օրը _____ օր/ամիս/տարի)

Հարցման սկիզբը _____ (ժամ/րոպե)

Հարցման ավարտը _____ (ժամ/րոպե)

Պատասխանը պետք է նշվի՝ շրջանակի մեջ վերցնելով տարբերակին համապատասխանող թիվը կամ լրացնելով տողերը

Ա. Դեմոգրաֆիկ տվյալներ

Նշեք Ձեր՝

(նշեք մեկ պատասխան)

1. Տարիքը. _____

2. Սեռը _____

    1. արական
    2. իգական

Բ. Դուրս գրման տեղեկություններ

Ստենտավորումից հետո՝

(նշեք մեկ պատասխան)

3. Ձեր բժիշկը Ձեզ դեղորայք նշանակե՞լ է

    1. այո
    2. ոչ   *(անցնել 5-րդ հարցին)*
    3. չգիտեմ/ չեմ հիշում   *(անցնել 5-րդ հարցին)*

4. Դուք ստացե՞լ եք պարզ և հասկանալի բացատրություն Ձեր դեղորայքն ընդունելու մասին (ընդունման ժամերի և դեղաչափերի վերաբերյալ)

    1. այո
    2. ոչ
    3. չգիտեմ/ չեմ հիշում

5. Հիշելով այն ժամանակաշրջանի մասին, երբ բուժում էիք ստանում սրտային հիվանդությունների վերականգնման համար, Դուք բժշկի հետ համաձայնեցնու՞մ էիք Ձեր հաջորդ հանդիպումը

1. հազվադեպ կամ երբեք
2. երբեմն
3. համարյա միշտ

6. Նշեք **բժշկի կողմից նշանակված** դեղորայքները, որ Դուք ընդունել եք

____Aspirin_____

____ (Plavix)_____

____Այլ (նշեք) _____

Գ. Հիվանդի բավարարվածություն

7. Դուք բավարար չափո՞վ էիք տեղեկացվածայն մասին, թե երբ և ինչ քանակությամբ դեղորայք ընդունել

(նշեք մեկ պատասխան)

1. այո
2. ոչ, կցանկանայի իմանալ մի քիչ ավելին
3. ոչ, կցանկանայի իմանալ շատ ավելին
4. ես որևէ դեղորայք չեմ ընդունել

8. Ինչքանո՞վ եք **համաձայն**, կամ **համաձայն չեք** հետևյալ պնդումներից յուրաքանչյուրի հետ.

(նշեք մեկ պատասխան` յուրաքանչյուր տողում)

	Լիովին համաձայն եմ	Համաձայն եմ	Դժվարանում եմ պատասխանել	Համաձայն չեմ	Բոլորովին համաձայն չեմ
Ա.Ընդհանուր Բավարարվածություն					
Իմ ստացած բուժօգնությունը կարելի է համարել կատարյալ	1	2	3	4	5
Ես դժգոհ եմ որոշ բաներից կապված իմ ստացած բուժօգնության հետ	1	2	3	4	5

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Բ.Շփման Վարվելակերպ					
Բժիշկների գործելակերպը իմ նկատմամբ շատ գործնական և անտարբեր է	1	2	3	4	5
Իմ բժիշկն ինձ վերաբերվում է շատ բարյացակամ և քաղաքավարի	1	2	3	4	5
Գ.Հաղորդակցություն					
Բժիշկները լավ են բացատրում բժշկական տեստերի անցկացման անհրաժեշտությունը	1	2	3	4	5
Բժիշկները երբեմն անտեսում են իմ ասածները	1	2	3	4	5

Դ. Առողջական վիճակ և առողջ վարքագիծ

(նշեք մեկ պատասխան)

9. Ինչպե՞ս կբնութագրեք Ձեր առողջական վիճակն ընդհանրապես

1. գերազանց
2. լավ
3. բավարար
4. վատ
5. շատ վատ

10. Համեմատած անցյալ տարվա հետ, ինչպե՞ս կգնահատեք Ձեր առողջական վիճակը հիմա

1. Հիմա շատ ավելի լավ, քան մեկ տարի առաջ
2. Հիմա որոշ չափով ավելի լավ, քան մեկ տարի առաջ
3. Համարյա միևնույնը, ինչ մեկ տարի առաջ
4. Հիմա որոշ չափով ավելի վատ, քան մեկ տարի առաջ
5. Հիմա շատ ավելի վատ, քան մեկ տարի առաջ

11. Դուք երբևէ սիգարետ ծխե՞լ եք

    1. այո
    2. ոչ   (*անցնել 14-րդ հարցին*)

12. Դուք ներկայումս ծխու՞մ եք

    1. այո
    2. ոչ   (*անցնել 14-րդ հարցին*)

13. Օրական միջին հաշվով քանի՞ սիգարետ եք ծխում   _____ սիգարետ

14. Բժիշկը երբևիցե ասե՞լ է ձեզ, որ Դուք ունեք հետևյալ առողջական խնդիրներից կամ վիճակներից որևէ մեկը

(նշեք բոլոր համապատասխան պատասխանները)

    1. Դիաբետ
    2. Արյան բարձր ճնշում
    3. Սրտային նոպա
    4. Այլ (նշեք)_____

Ե. Նշանակված դեղորայքի համապատասխան ընդունում

Մտածելով Ձեր` <u>բժշկի կողմից նշանակված</u> դեղորայքի մասին, պատասխանեք խնդրեմ հետևյալ հարցերին.

(նշեք մեկ պատասխան)

15. Դուք երբևիցե մոռանու՞մ եք ընդունել Ձեր դեղորայքը

    1. այո
    2. ոչ

16. Դուք անուշադի՞ր եք Ձեր դեղորայքն ընդունելու ժամանակի մասին

    1. այո
    2. ոչ

17. Երբ Ձեզ լավ եք զգում, երբևիցե դադարեցնու՞մ եք Ձեր դեղորայքի ընդունում

    1. այո
    2. ոչ

18. Երբեմն երբ Ձեզ վատ եք զգում դեղորայք ընդունելիս, Դուք երբևիցե դադարեցնու՞մ եք դեղորայքի ընդունումը

1. այո
2. ոչ

19. Ի՞նչն է հանդիսացել ն2անակման չհետնելու պատճառը

1. Անկարող էի գնել դեղորայք(ներ) գնի պատճառով
2. Անկարող էի գնել դեղորայք(ներ) համապատասխան դեղորայքի բացակայության պատճառով
3. Անկարող էի գնել դեղորայք(ներ) հեռավորություն ճանապարհորդելու պատճառով
4. Կողմնակի էֆեկտներ/Վախ կողմնակի էֆեկտներից
5. Մոռացել եմ դեղորայք(ներ) ընդունել
6. Դեղորայքները չեն օգնում
7. Այլ (Ն2եք)_____

Ջ. Սոցիալ- դեմոգրաֆիկ տվյալներ

Ն2եք Ձեր՝

20. Ազգությունը

1. հայ
2. ռուս
3. եզդի
4. այլ (Ն2եք) _____

21. Ամուսնական կարգավիճակը

1. ամուսնացած
2. ամուրի
3. ամուսնալուծված
4. այրի
_____

22. Ձեր ստացած կրթության ամենաբարձր մակարդակը

1. թերի միջնակարգ (10 տարուց պակաս)
2. միջնակարգ (10 տարի)
3. միջնակարգ մասնագիտական (10-13 տարի)
4. համալսարան, ԲՈՒՀ
5. հետդիպլոմային

23. Ներկայումս դուք աշխատու՞մ եք

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1. այո
2. ոչ   (*անցնել 25-րդ հարցին*)

24. Ո՞րն է լավագույնս բնութագրում Ձեր կարգավիճակը

   1. գործազուրկ եմ, աշխատանք եմ փնտրում
   2. գործազուրկ եմ, աշխատանք չեմ փնտրում
   3. չեմ կարող աշխատել (մշտական) հաշմանդամության պատճառով
   4. չեմ կարող աշխատել մանկան խնամքը ապահովելու անկարողության պատճառով
   5. ուսանող եմ/դպրոց եմ հաճախում
   6. տնային տնտես(ուհի) եմ
   7. թոշակառու եմ
   8. ձեռներեց եմ
   9. ֆերմեր եմ
   10. այլ (նշեք) _____

25. Անցյալ ամիս Ձեր ընտանիքի բոլոր անդամների կողմից ունեցած միջին ամսեկան եկամուտը կազմել է`

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

Appendix 3. Consent Form (English & Armenian)

Oral Consent Form

Title of Research Project: Patient Satisfaction and Medication Noncompliance following Percutaneus Coronary Intervention in Armenia

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Explanation of Research Project:

Hello, My Name is Seda Aghabekyan. I am a second year student of Public Health Department at American University of Armenia. As a part of my Master Project I am conducting a research study to assess patient satisfaction at Nork-Marash Medical Center following stent placement. You are asked to participate in the study because you are one of *375* randomly selected patients, who had a procedure involving a stent at NMMC.

If you do not mind, I am going to ask you some questions related to your health, satisfaction and medication compliance. Questions will not be of personal or of a sensitive nature and will not cause any harm to you. Your participation is highly valued by NMMC. The interview will take less than 15 minutes.

There are no any risks for you to participate in this study. Your participation or refusal is not connected with your further treatment at the center. The only inconvenience will be your time spent on the interview but you will not be compensated for your time. You will not receive any benefits from your participation but your answers will contribute to the further improvement of the quality of health services of NMMC.

Your confidentiality will be assured. Only I, as a researcher, will have access to personal identifiers with names and phone numbers of the study participants. And these identifiers will be destroyed after the study is finished. Information will only be reported in an aggregate/summarized form and it will not be possible to identify your responses in the report.

Participation in this survey is voluntary and you can withdraw from the study at any time you want.

If you would like to get more information you can contact Varduhi Petrosyan, Associate Dean, College of Health Sciences: (010) 51 25 64, e-mail: vpetrosi@aua.am or the student investigator Seda Aghabekyan, (091) 221998, e-mail: seda_aghabekyan@edu.aua.am. If you want to talk to anyone about the study as you feel that you have been treated unfairly or have been hurt, you can contact Yelena Amirkhanyan, the chair of Institutional Review Board: (010) 512592, e-mail: yamirkh@aua.am.

Հարցման մասնակցության համաձայնագիր

Հետազոտության անվանում ՝ Հիվանդների բավարարվածությունն ու նշանակված դեղորայքի համապատասխան ընդունումը ներմաշկային կորոնար միջամտությունից (ստենտավորումից) հետո Հայաստանում:

Հետազոտության բացատրություն

Բարև Ձեզ, իմ անունը Սեդա Աղաբեկյան է: Ես Հայաստանի Ամերիկյան Համալսարանի Հանրային առողջապահության ֆակուլտետի ավարտական կուրսի ուսանող եմ: Որպես իմ դիպլոմային աշխատանքի մի մաս, ես հետազոտություն եմ կատարում, գնահատելու հիվանդների բավարարվածությունը ստենտավորումից հետոՆորք-Մարաշ բժշկական կենտրոնում (ՆՄԲԿ): Ձեզ խնդրում եմ մասնակցել այս հարցմանը, քանի որ դուք ներառվել եք այն 375 պատահականորեն ընտրված մարդկանց շարքում, որոնք ստենտավորվել են ՆՄԲԿ-ում:

Եթե Դուք դեմ չեք, ես Ձեզ մի քանի հարց կտամ՝ կապված Ձեր առողջության, բավարարվածության և նշանակված դեղորայքի համապատասխան ընդունման հետ: Հարցերը անձնական կամ նուրբ զգայական բնույթի չեն և Ձեզ ոչ մի վնաս չեն պատճառի: Ձեր մասնակցությունը բարձր կգնահատվի ՆՄԲԿ-ի կողմից: Հարցումը կտևի 15 րոպեից քիչ:

Այս հետազոտությանը մասնակցելով Դուք որևէ ռիսկի չեք դիմում: Ձեր մասնակցությունը կամ հրաժարումը ոչ մի կերպ չի անդրադառնա կենտրոնում Ձեր հետազա բուժման հետ: Ձեզ պատճառած միակ անհարմարությունը կապված է այն ժամանակի հետ, որը կտրամադրեք հարցագրույցին, բայց Դուք դրա համար չեք փոխհատուցվի: Ձեր մասնակցությունից Դուք որևէ շահույթ չեք ունենա, բայց Ձեր պատասխանը կնպաստի ՆՄԲԿ բուժծառայությունների որակի հետագա բարելավմանը:

Ձեր գաղտնիությունը կապահովվի: Միայն ինձ, որպես հետազոտող, հասանելի կլինի հետազոտության մասնակիցների ինքնությունը հաստատող տվյալները՝ անունները և հեռախոսահամարները: Այս տվյալները կոչնչացվեն անմիջապես հետազոտության ավարտից հետո: Ձեր կողմից տրամադրված անձնական տեղեկատվությունը կգեկուցվի միայն ամփոփ ձևով, և Ձեր պատասխանները գեկույցում տարբերակել հնարավոր չի լինի:

Մասնակցությունը ըստ ցանկության է, և Դուք կարող եք դադարեցնել հարցագրույցը ցանկացած պահի:

Եթե Դուք կցանկանաք ստանալ ավելի մանրամասն տեղեկություններ, ապա կարող եք դիմել Վարդուհի Պետրոսյանին՝ Առողջապահական գիտությունների բողեջի

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փոխղեկանին, (010) 51 25 92, էլ-փոստ՝ *vpetrosi@aua.am*, կամ ինձ՝ Սեդա Աղաբեկյանիս, (091) 221998, էլ-փոստ՝ seda_aghabekyan@edu.aua.am: Եթե Դուք ցանկանաք խոսել հետազոտության մասին, քանի որ գտնում եք, որ Ձեզ ոչ ազնիվ կամ վատ են վերաբերվել ապա կարող եք զանգահարել Ելենա Ամիրխանյանին՝ էթիկայի հանձնաժողովի նախագահին, (010) 51 25 92, էլ-փոստ՝ yamirkh@aua.am: