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ONE YEAR EVENT-FREE SURVIVAL FOLLOWING CORONARY STENT REVASCULARIZATION IN NORK MARASH MEDICAL CENTER, YEREVAN, ARMENIA

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Abstract

Background. Coronary stent revascularization is the most prevalent method of percutaneous coronary intervention. The study evaluated the outcomes and the treatment compliance of patients following stent placement at Nork Marash Medical Center.

Methods. Study involved 160 patients who underwent stent placement at NMMC during 2003, with de novo stenosis of native coronary arteries. Patients with severe valvular disease and ejection fraction <=25% were excluded from the study. Pre-procedural and peri procedural information was abstracted from medical records. Follow-up information was obtained via telephone interview and from follow-up forms.

Results. A total of 184 stents were placed in 160 patients with average of 1.17 stents per patient (sd=0.41). Acute event rate was 2.5%. Complete revascularization was achieved in 61.9% of stented patients. The mean follow-up period was 14 ± 5.5 months. At 12 months, freedom from death was 98.8%; from nonfatal MI 99.2%; and from repeat revascularization 94.1%. Freedom from the composite outcome of death/nonfatal MI was 97.9%, death/repeat revascularization was 92.9%, and death/nonfatal MI/repeat revascularization was 92.1%. The angina recurrence rate was 36.3%. Two independent predictors for this outcome were: incomplete revascularization (OR=2.2), and bare metallic stents (OR=3.3). Interviewed patients were prescribed aspirin (92.2 %), beta-blockers (60.8%), Angiotensin Converting Enzyme Inhibitors (43.0%), and statins (40.6%). Higher rates of non compliance were reported for beta-blockers and statins (12.9%; 14.6%) as compared to other drugs. The majority of respondents (87.5 %) were counseled on diet, of which 86.7% reported compliance. Almost half of the smokers (49.4 %) quit smoking after stent procedure.

Conclusions. Coronary stent placement at NMMC during 2003 resulted in a low rate of inhospital complications and high one year event-free survival rates for specified outcomes. However, about one-third of the population experienced angina recurrence. Increase use of drug-eluting stents was suggested. Additional efforts should be directed toward increasing patient compliance with prescription, including medication, diet, and smoking habits.

1. INTRODUCTION/BACKGROUND INFORMATION

Percutaneous coronary intervention (PCI) is now the most frequently used revascularization technique for the effective management of multivessel coronary artery disease (1). Although initially limited to percutaneous transluminal coronary angioplasty (PTCA), PCI now includes other new approaches relieving coronary artery narrowing such as implantation of intracoronary stents and other catheter devices, rotational or directional atherectomy, laser angioplasty, etc (1). 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 (1). Coronary stent revascularization is superior to PTCA with respect to both short term (procedural safety) and long-term (reduced rates of restenosis, repeat revascularization) outcomes (1-4). The efficacy of stents versus balloon angioplasty to reduce restenosis rate have been studied in as many as 6300 patients in 12 different randomized clinical trials (1).

The outcomes of coronary stent revascularization were compared with the same outcomes following coronary artery bypass grafting (CABG) including long-term and short-term survival, length of hospital stay, complete revascularization rate, cardiac events, treatment associated costs, treatment efficacy, etc (5-10). Although coronary stent revascularization could be performed with high procedural success rate and acceptable late clinical outcomes (survival, death, cardiac or cerebrovascular events), the rates of angina recurrence and the need for target lesion revascularization were significantly higher in the stent group as compared to CABG (8,11). In usual decision making process, the main reasons for a physician to favor CABG over stent were factors like left main artery stenosis, total coronary occlusion, poor ejection fraction (< 25%), small coronary arteries, angioplasty failure, and the need for a combined surgical procedure (5). Another important consideration favoring CABG over stent was diabetes mellitus (12).

Acute complications after coronary stent placement procedure include death, stent occlusion, acute myocardial infarction (AMI), stroke, emergency CABG, vascular access site complications, contrast agent nephropathy, etc (1). According to the American College of Cardiology/American Heart Association (ACC/AHA) guidelines for percutaneous coronary intervention (2001) emergency CABG rates usually vary from 0.2 to 3%, and unadjusted inhospital mortality rates from 0.5 to 1.4% (1). The probability of one-year freedom from death or myocardial infarction was reported as 96.6%, while freedom from death, myocardial infarction, and repeat revascularization was 79.8% (2). Freedom from severe angina during one-year follow-up was 79% (2). The independent predictive factors of combined major adverse cardiac events (death, myocardial infarction, and repeat revascularization) after the procedure were advanced age, diabetes mellitus, left ventricular dysfunction, lesion characteristics like location and complexity, and total length of stent (13-15). Another important factor is the completeness of revascularization achieved during the procedure (16). The risk of acute procedural failure decreases with growing institutional experience with this procedure (13).

Restenosis after stent placement still is the major determinant of event-free survival (1, 14, 17). Recently introduced drug eluting stents have been shown to significantly reduce restenosis after coronary angioplasty with stent implantation (3, 5,18). Important predictors of restenosis include lesion complexity, lesion location in left anterior descending or left circumflex coronary artery, a tighter and longer stenosis before intervention, a greater number of stents implanted, and the presence of stent overlap, as well as diabetes mellitus and

multivessel disease (14, 19). Nevertheless, with the annual increase of number of patients with coronary stent revascularization, the proportion of those who need target-vessel revascularization tends to decline (20).

Patient compliance with treatment is another factor influencing outcomes. Ischaemic hearth disease (IHD) is a chronic condition and should be managed by the patient continuously. The prescribed treatment for IHD includes lifestyle modifications (smoking, diet, physical activity), regular intake of specific drugs, and regular follow-up visits with diagnostic procedures when needed. Noncompliance can result in unnecessary admissions (up to 10% of total hospital admissions), increased treatment-associated costs, and a decrease in patient quality of life (21). Moreover, according to an estimate from the Office of the U.S. Inspector General, each year patient noncompliance results in 125,000 deaths from cardiovascular disease (21).

Nork Marash Medical Center is a leading cardiac surgical center in Armenia with established outpatient and inpatient services. Different strategies of PCI are practiced in the Center since the establishment of the cardiac catheterization laboratory in 1996. Gradual increases resulted in more than 1300 diagnostic and 200 interventional procedures in 2003. Considering the efforts toward continuous quality improvement at the center, the evaluation of the outcomes of coronary stent revascularization at NMMC was imperative. The present study measured one year event-free survival of patients who underwent coronary stent revascularization at NMMC during 2003, assessed the outcomes and patient treatment compliance.

Research questions of the study were:

- What is one year event free (free from death, MI, repeat revascularization) survival rate of coronary stent revascularization in patients treated at the Nork-Marash Medical Center (NMMC) during 2003?
- What factors are predictive for adverse outcomes of the procedure?
- What is patient compliance with treatment following coronary stent revascularization?
- What is patients' health perception after one year of the procedure?

The study objectives were the following:

- Measure one year event free survival of study population for different single and composite events (death, MI, repeat revascularization)
- Identify factors predictive for adverse outcomes
- Assess patient compliance to prescribed treatment
- Assess patients' health perception after 12 month or more following the procedure

2. METHODS

2.1. Study design

Background, procedural, and follow-up information about patients who underwent stenting at NMMC in 2003 was collected by retrospective review of medical records and follow-up forms. This was followed by a cross-sectional telephone survey in November-December, 2004 among patients included in the sample (excluding patients who died or passed CABG during the follow-up period).

2.2. Study protocol

Quality Assurance Project coordinators in cooperation with an adult cardiologist (interventionist) and an adult cardiology fellow from NMMC performed the medical record reviews. Then the patients were contacted by phone. Patients who reported current complaints of chest pain were advised to visit the clinic for further examination and treatment.

2.3. Study instruments

Two separate instruments were developed for the study. Questionnaire 1 was developed to abstract the needed data from medical records (Appendix 1). Questionnaire 2 was constructed for telephone surveys (Appendix 2). The questions of Questionnaire 2 related to patient complaints regarding chest pain were taken from the Patient Follow-up questionnaire previously validated at the center (22). Two questions assessing current health status of patients were taken from the Armenian version of Short Form-36 (22). However, to assure the logical flow of questions, Questionnaire 2 was pre-tested among 10 patients who underwent coronary stent placement at NMMC in 2004.

2.4. Study population

The inclusion criteria were the following:

- All patients undergoing percuteaneous coronary intervention (PCI) with stent placement from January 1, 2003 to December 31, 2003 at NMMC, with de novo stenosis of native coronary arteries.

Exclusion criteria were:

- Patents with severe valvular heart disease
- Patients with poor ejection fraction (<=25%)
- Patients who underwent stent placement after AMI as bridging procedure to CABG surgery

The follow-up information of patients who underwent CABG procedure after stent revascularization was collected until the date of surgery. There was no need for sample size calculation as the study had mainly descriptive purposes and utilized all valid cases during the study period.

2.5. Definitions

Complete revascularization was defined as a successful management of the index vessel with no residual >50% stenosis in any other coronary arteries.
Number of diseased coronary vessels was defined as the number of major coronary vessel systems (Left Anterior Descending, Left Circumflex, Right) with >50% narrowing in any angiographic view.
Acute inhospital adverse events included all events occurred during the hospital stay for current stent placement procedure.
Acute myocardial infarction (AMI) was diagnosed when cardiac enzymes (creatine kinase-MB) were elevated >=3-fold with chest pain >=30 minutes and/or with the appearance of new specific changes on electrocardiography (ECG).
One year follow-up events included death, nonfatal MI, repeat revascularization (either percutaneous coronary intervention or CABG), and composite outcomes such as death/nonfatal MI; death/repeat revascularization; and death/nonfatal MI/repeat revascularization (so called major adverse cardiac events (MACE)).

Restenosis was defined as >= 50% intra stent or edge stenosis after the procedure.
New lesion was defined as a new >= 50% narrowing outside the stent.
To confirm the diagnosis of *angina recurrence* the staff cardiologist incorporated patient complaints on specific ischaemic chest pain with the available objective data (ECG and/or treadmill tests).

2.6. Technique of procedure

All procedures were performed with standard techniques. Intracoronary stent implantation was performed with a rapid-exchange delivery system. Noncompliant or minimally compliant balloons were inflated at sizes equivalent to or slightly larger than nominal stent size (10 to 16 atm) with the goal of achieving no residual stenosis. Predilatation before stenting usually was performed with an undersized angioplasty balloon. The stents were then deployed with inflation of the stent delivery balloon, and further dilatation was additionally performed if needed. All patients were kept in the coronary care unit for at least 24 hours after the stenting procedure.

2.7. Anticoagulation

All patients received at least 100 mg oral Aspirin beginning 12 hours before the procedure and continued indefinitely. Intravenous Heparin was administered at a dose of 50-100 units/kg as a bolus before the procedure and was followed by 1000units/hours infusion within 12 hours. Treatment with Ticlopidine, at a dose of 250 mg twice daily, was begun 1-3 days before the procedure and continued 6-8 weeks thereafter.

In patients admitted with AMI, an infusion of Glycoprotein IIb/IIIa inhibitor Tirofiban (Aggrastat) was performed at a dose of 10 μg/kg during first 3 minutes, followed at a dose of 0.15 μg/kg throughout 18-24 hours after stenting procedure, in addition to intravenous Heparin, oral Aspirin, and Ticlopidine.

2.8. Clinical Follow-Up

Generally, after stenting procedures all patients are assigned follow-up visits to the outpatient Adult Cardiology Clinic (ACC) once a month for the first six months, once at the end of 12th month, and annually thereafter. For the study, as a first step, the patient follow-up information was obtained from the follow-up forms at the ACC. Then direct telephone interviews were conducted with patients to assess their current health status, compliance with treatment, and identify/check any event(s) that occurred during the follow-up period, either recorded in ACC forms or not. In case if a patient complained of typical chest pain at the time of the interview, he/she was called to visit the clinic for needed examinations. In case when contacting the patient was not possible, the follow-up information was censored at the patient's last visit to the clinic.

3. ETHICAL CONSIDERATIONS

The research proposal was reviewed and approved by the Institutional Review Board (IRB) #1 of the American University of Armenia. Oral consent was obtained from patients prior their participation in the telephone interview. The study possessed minimal risk for patients. The questions included in the interview composed a part of the usual follow-up care at NMMC. In the case if a patient visited the clinic after the interview, he/she was treated as it would be a usual follow-up visit. Only summary data was reported.

4. STUDY LIMITATIONS

One of the limitations of the study was that different types of stents were used. Moreover, at the time when these patients underwent the procedure, the lesions were not classified at the center according to the modified ACC/AHA grading system as type A, B, or C. So, the stratification of patients in accordance with the risk of procedure they underwent was not completely estimated. Another limitation was that not all patients underwent repeat coronarography for objective evaluation of the outcomes. Repeat coronarography was conditioned by different factors (patient complaints, physician judgment, patient compliance to follow-up regimen/prescribed tests). Thus, the number of patients with restenosis and/or new lesion(s) revealed by this study could be underestimated. Correspondingly, in the case if all patients underwent repeat coronarography, the number of patients with repeat revascularization might be larger.

5. DATA ANALYSES

Study team performed single data entry using SPSS 11.0 statistical package. Range checking was performed to assure accuracy of entered data. STATA 7.0 and SPSS 11.0 were used for data analyses. Frequencies were used to summarize categorical data, and mean ± standard deviation to summarize continuous variables. Further, X^2 test results for categorical data and t-test results for continuous data were obtained. Survival analyses for the specified events (MI, death, repeat revascularization, and different composite outcomes) were performed using Kaplan-Meier curves. Log rank test was used to identify potential predictors of MACE.

6. RESULTS

6.1. Administrative data

Overall, 167 patients underwent coronary stent revascularization at the center in 2003. Of these patients, seven did not meet the inclusion criteria. The total sample size consisted of 160 patients. Patients who experienced CABG after the stent revascularization were followed until the date of their surgery (n=6). They were not involved in the telephone interview.

The response rate for telephone interview was 73.7% (112 out of 152 eligible patients). For 19.6 % of remaining patients telephone number was not available/not responding, 6.5% were out of the country, and 1.3 % refused to participate in the interview.

6.2. Acute inhospital events

Acute event rate was 2.5% (n=4 out of 160). Acute events were the following: death (n=2, 1.25%), emergency CABG (n=1, 0.63%), subacute stent thrombosis (n=1, 0.63%).

6.3. Patient and procedural characteristics

Mean age of study population was 52.8 years (sd=9.5) and ranged from 32 to 79 years. Other characteristics are presented in Table 1.

Table 1. Patient characteristics (n=160)

Patient characteristics	Frequencies (%)	Patient characteristics	Frequencies (%)
Male sex	86.9	**EF**	
Valvular heart disease	12.5	Good (>=50%)	56.9
Stable angina	19.9	Impaired (26-49%)	43.1
Acute coronary syndrome	77.3	**Number of diseased vessels**	
CHF	10.6	Single vessel	61.6
Patient characteristics	**Frequencies (%)**	**Patient characteristics**	**Frequencies (%)**
Previous MI	29.8	Two vessels	25.8
Acute MI	30.4	Three vessels	12.6
Previous PCI	5.0	**Diseased coronary vessels**	
Previous CABG	7.5	LAD	66.9
Hypertension	46.9	LCX	40.6
Diabetes	11.9	RCA	44.1

CABG, coronary artery bypass grafting; CHF, congestive hearth failure; EF, ejection fraction; MI, myocardial infarction; LAD, left anterior descending; LCX, left circumflex artery; PCI, percutaneous coronary intervention; RCA, right coronary artery

Total number of the placed stents was 184 with 1.17 $\pm$ 0.41 stents per patient (range from 1 to 3). Table 2 presents the distribution of placed stents in coronary arteries. Left anterior descending (LAD) was the most frequently stented vessel.

Table 2. Stented cardiac vessels

Target vessels	Stents (%) n=184
LAD	45.1
LCX	26.1
RCA	28.8

LAD, left anterior descending; LCX, left circumflex artery; RCA, right coronary artery

About 61.4% of patients underwent complete revascularization. Mean stent diameter was 3.18 mm (sd=0.36) within the range from 2.5 to 4 mm. Mean stent length was 17.1mm (sd=4.36) with the range from 8 to 28mm.

The following types of stents were used in this patient population: Bx Sonic (*Johnson & Johnson Corp,* n=122); Cypher (*Johnson & Johnson Corp,* n=31); Multilink Penta *(Guidant,* n=22); and AVE (*Medtronic*, n=9). The majority of stents were bare metallic, and only 16.9% was drug-eluting (Cypher).

Hospital readmission rate for heart related health conditions among the interviewed patients was 11.5% (4 patients were admitted to NMMC and 9 patients to other hospitals).

6.4. Event-free survival rates at 12 months

The mean duration of the total follow-up period was 14 ± 5.5 months with the range from 0.17 to 23.1 months. During the total follow-up period there was 1 case of nonfatal MI, 9 cases of repeat revascularization (CABG (n=6) or stent placement (n=3)), and 3 patients died. The rate of freedom from death at 12 months was 98.8% (confidence interval (CI), CI 95.1% - 99.7%); freedom from nonfatal MI was 99.2% (95% CI, 94.7%-99.9%); and freedom from repeat revascularization was 94.1% (CI 88.9%-96.9%) (Figure 1). The freedom from the

composite outcome of death/nonfatal MI was 97.9% (CI 93.9%-99.4%); death/repeat revascularization 92.9% (CI 87.5%-95.9%), and death/nonfatal MI/repeat revascularization (MACE) was 92.1% (CI 86.5%- 95.4%) (Figure 2).

Figure 1. One year event-free survival (Death, Myocardial Infarction, Repeat Revascularization)

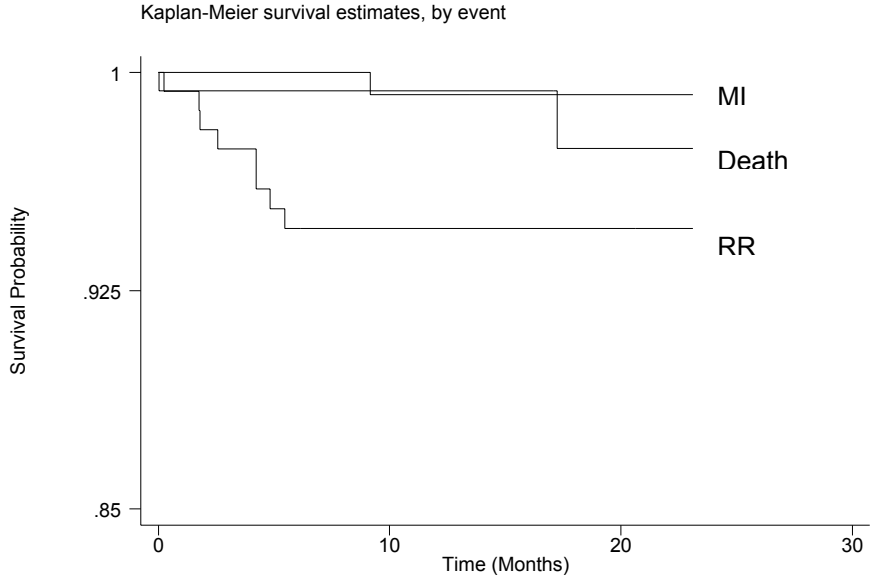
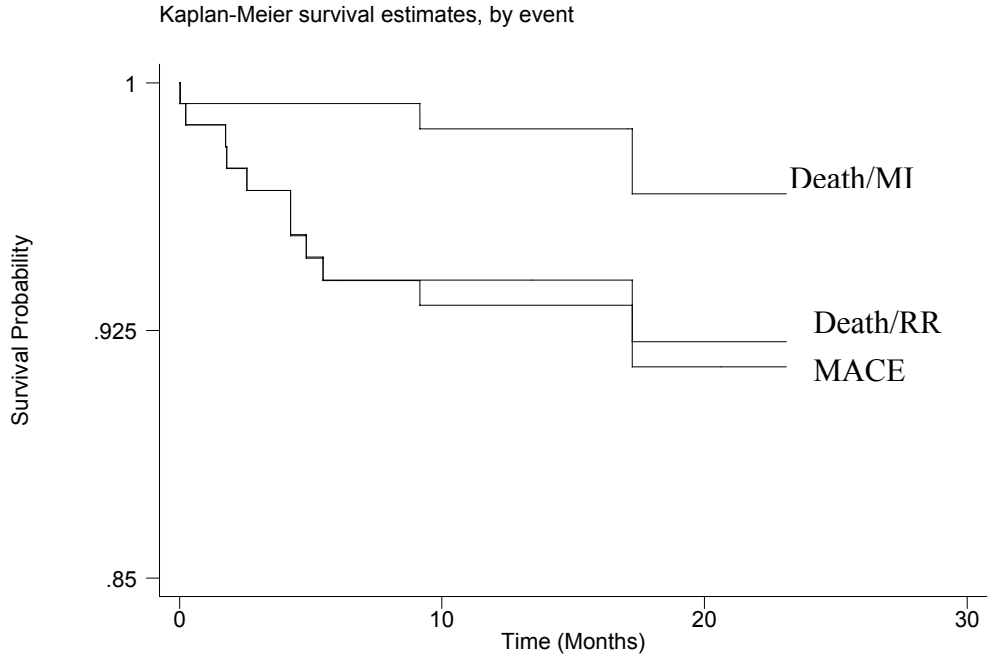


Figure 2. One year event-free survival (Death, Myocardial Infarction, Repeat Revascularization)



Neither the factors presented in Table 1, nor patient age and stent characteristics were significantly associated with the occurrence of MACE in this patient population.

6.5. Repeat coronarography and repeat revascularization

Out of 160 patients, 27 (16.9%) underwent repeat coronarography following stent placement. The procedure was performed only in high risk patients based on their complaints and objective data. Table 3 presents the results of repeat coronarography.

Table 3. Results of repeat coronarography (n=27)

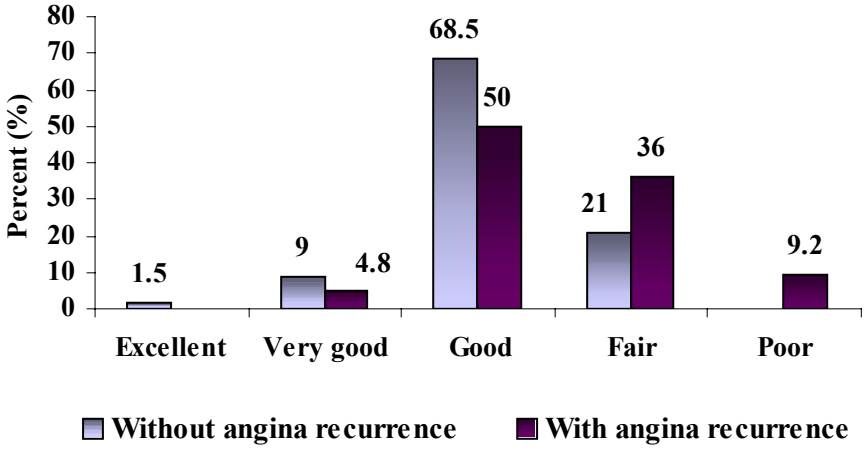
Results	Frequency (%)
Restenosis	9 (33.3)
Restenosis, new lesion	1 (3.7)
Normal stent, new lesion(s)	9 (33.3)
Normal stent	8 (29.6)

The restenosis rate was 37.0 % (n=10) among the patients who underwent repeat coronarography. Among those who underwent repeat coronarography, the restenosis rate was significantly higher in patients stented by bare metallic stents as compared to those stented with drug eluting stents (p=0.03). During the follow-up period, only four of the patients with restenosis underwent repeat revascularization. Besides these patients, three other patients with normal stents but new occlusions also passed repeat revascularization. One patient underwent repeat revascularization in another hospital and the result of the repeat coronarography was not available.

6.6. Angina recurrence

From all participants of the telephone interview (n=112), about 46.5% reported that at some point after the procedure they had pressing or burning pain in the chest. Only 59.2% of them mentioned that the pain was similar to the one they had before the procedure. As for the duration of pain, 63.8% of patients with pain described it as less than 30 minutes. Patients with angina recurrence reported significantly worse own health perception at the time of the interview (p-value of X^2 statistics was 0.024) as compared to patients without that outcome (Figure 3).

Figure 3. Health perception of patients with and without angina recurrence at the time of the interview



For patients who did not participate in the telephone interview, the combined objective and subjective follow-up data enabled to make final conclusion about angina recurrence. Finally, **35.6%** (n=57) of patients were diagnosed by the cardiologist as having angina recurrence. All

the patients who experienced MACE during the follow-up period, experienced angina recurrence before the event.

After exploring the possible predictors of angina recurrence, the significant factors were entered into the multiple logistic regression model to assess their independent association with the outcome (Table 4).

Table 4. Independent predictors of angina recurrence

Covariates	OR	*p* value	CI
Incomplete revascularization	2.2	0.027	1.10 – 4.40
Bare metallic stents	3.3	0.027	1.14 – 9.51

Patients with incomplete revascularization had about 2.2 times higher risk of developing angina recurrence than patients who underwent complete revascularization. Drug-eluting stents had protective effect on angina recurrence in contrast with bare metallic ones.

6.7. Patient compliance with treatment

Patient compliance with treatment was evaluated among interviewed patients (n=112). This included smoking cessation, diet, and medication use after stent procedure.

Smoking habits and cessation

Out of 112 respondents, 37.2% (n=42) were current smokers with an average 15.7 $\pm$ 10.3 smoked cigarettes daily. The percentage of patients smoking before stent placement was 73.2% (n=83). So, by the time of interview **49.4%** of smokers quit smoking. The decrease in the smoking rate was statistically significant ($p < .0001$).

Adherence to diet

The majority of telephone interview respondents (94.6%) reported that they have checked their blood cholesterol levels at least once (3.6% never checked, and 1.8% did not remember). From patients who checked their blood cholesterol levels, 76.4% mentioned that they ever had elevated blood cholesterol level, 17.8% mentioned that they had normal level, and 5.7% did not know the test results. About **87.5%** of interviewees mentioned that they were counseled on diet at NMMC. At the time of the interview, **86.7%** of the respondents reported that they completely/partially follow the recommendations on diet.

Compliance with prescribed medication

Patients were asked about the prescribed medication after their last visit to clinic, and whether they continue to take the medication. Table 4 presents the results.

Table 5. Patient compliance to prescribed medication

Medication	Prescribed (%)	Among prescribed patients		
		Taken (%)	Not Taken (%)	Stopped by doctors' recommendation (%)
Aspirin	92.2	91.6	7.4	1.1
BB	60.8	80.6	12.9	6.5
ACEI	43.0	90.7	7.0	2.3
Statins	40.6	80.5	14.6	4.9

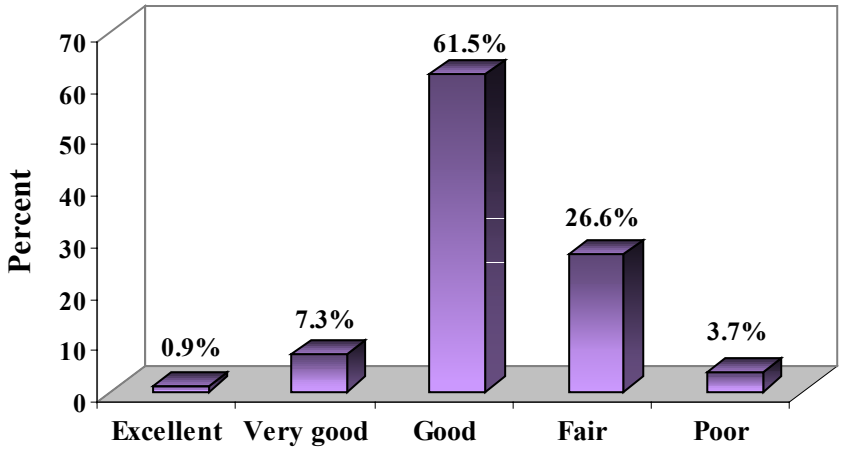
ACEI, Angiotensin Converting Enzyme Inhibitors; BB, Beta Blockers

The highest rate of non compliance with medication was observed for statins (14.6%), followed by beta blockers (12.9%). These drugs were also more frequently stopped by physician recommendation as compared to aspirin and Angiotensin Converting Enzyme Inhibitors (ACEI).

6.8. General health perception

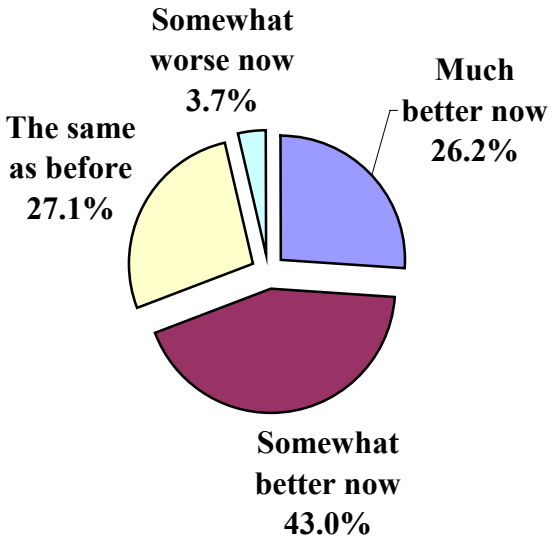
The last two questions of the telephone interview were taken from the SF-36 questionnaire. First, patients evaluated their health in a five-item scale from excellent to bad. The results are shown in the Figure 4. About two-third of the responses were in the range from excellent to good.

Figure 4. Current health status



Second, the respondents were asked to evaluate their present health status as compared to the one before the stenting procedure. None of the patients identified their present health status as "much worse". Only 3.7% of patients reported somewhat worse health status at present than it was before the procedure, and 27.1% reported is as the same as before (Figure 5).

Figure 5. Current health status compared to health status before stent replacement



7. DISCUSSION & CONCLUSION

The study revealed that acute inhospital adverse event rate after coronary stent revascularization at the center is low. The rates of inhospital death (1.25%) and emergency CABG (0.63%) were in the acceptable ranges indicated by ACC/AHA guidelines for percutaneous coronary intervention (2001). One year event-free survival rate of patients after coronary stent revascularization allows evaluating the mid-term results of this procedure at the center. For identified events, either single (death, nonfatal MI or repeat revascularization) or composite (including all three events as MACE), the one year event-free survival rates were high. The lowest survival rate was 92.1% measured for MACE. The relatively small sample size and the duration of follow-up did not allow revealing any significant predictor of the survival from any event. However, this opens a door for further studies and evaluations.

Many previous studies showed that angina recurrence is one of the most frequent events after a coronary stent revascularization (8,11). The assessment of completeness of any angioplastic procedure is one of the predictors for this event (16). More than one-third of the study population experienced angina recurrence after the procedure, which could be identified as one of the main findings of the study. Moreover, in the case if the response rate to the telephone interview was higher than in this study (73.7%), the rate of angina recurrence could have been higher, too. Incomplete revascularization increases the likelihood of having angina recurrence after the procedure.

Another predictor was the type of the stent used. Many controlled randomized trials have shown the benefits of drug-eluting stents over bare metallic stents (3, 5,18). The availability of drug-eluting stents is increasing and, subsequently, more patients are treated with these stents. In 2004 of all placed stents at NMMC, 40% were drug-eluting while the latter composed only 17% in 2003. Evidently, if continued this tendency would further decrease the number of patients with angina recurrence, which in its turn, would improve their perception of the general health and quality of life.

The study revealed interesting patterns of patient compliance with prescribed treatment. Considering the significant decrease in smoking rates after the procedure, the efforts of the staff in smoking cessation counseling could be evaluated as satisfactory (about half of the smokers quit the habit). However, more efforts should be undertaken to persuade all smokers to quit the habit after the procedure and to make the change in behavior sustainable. Most of the surveyed patients checked their blood cholesterol level, and followed the prescribed diet.

Particular attention should be paid to the prescribed medication after the stenting procedure. Almost all patients were prescribed aspirin and reported high compliance. Only about two-third of patients were prescribed beta-blockers. These drug users also reported high non-compliance rate (12.9% from prescribed patients). According to hospital physicians, one of the possible reasons could be development of side effects and bad tolerance of the drug by patients. Another possible cause could be the fear of many patients to develop impotence after the long use of the drug, although physicians stated that the most often the patients amplify the risk of this complication.

ACEI were prescribed to only 43% of patients, and had high compliance rate. The prescription of statins remains a concern at the center. The study revealed that only 40.6% of patients were prescribed statins, and about 15% do not comply with this prescription. The low

percent of patients who were prescribed statins underlined the importance of adopting some general treatment guidelines at the center, which should be updated periodically using evidence-based approaches. One of the reasons for non-compliance with this drug is that statins are costly in Armenia and the majority of the patients cannot afford them for long period of time.

About 70% of the interviewed patients assessed their own general health as ‘excellent’ or ‘good’. About two-third of interviewed patients reported better health as compared to the time prior to the procedure.

The results of this study could be used as a benchmark for other similar centers in Armenia and in the region. Further follow-up of the study population may provide data on late outcomes of the procedure. More efforts should be made to improve patient treatment after stenting procedure, especially in terms of improving prescription patterns of beta-blockers and statins. Hopefully, the proportion of patients treated with drug-eluting stents will continue to increase in the center resulting in better outcomes. Additional efforts should be directed toward increasing of patient compliance with recommendations, including medication, diet, and smoking habits.

REFERENCES

1. Smith SC, Jr, Dove JT, Jacobs AK, Kennedy JW, Kereiakes D, Kern MJ, Kuntz RE, Popma JJ, Schaff HV, Williams DO. ACC/AHA guidelines for percutaneous coronary intervention: 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). J Am Coll Cardiol 2001; 37:2239i-lxvi
2. Mathew V, Garratt KN, Holmes Jr DR. Clinical outcome after multivessel coronary stent implantation. Am Heart J 138(6):1105-1110,1999.
3. Moses JW, Leon MB, Popma JJ, Fitzgerald PJ, Holmes DR, O'Shaughnessy C, Caputo RP, Kereiakes DJ, Williams DO, Teirstein PS, Jaeger JL, Kuntz RE. Sirolimus-eluting stents versus standard stents in patients with stenosis in a native coronary artery. N Engl J Med 2003;349:1315-23.
4. Pepine CJ, Holmes DR. Coronary artery stents. JACC 1996;28(3):782–94
5. Ferreira AC, Peter AA, Salerno TA, Bolooki H, Marchena E. 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
6. Unger F, Serruys PW, Yacoub MH, Ilsley C, Paulsen PK, Nielsen TT, Eysmann L, Kiemeneij F. Revascularization in multivessel disease: comparison between two-year outcomes of coronary bypass surgery and stenting. J Thorac Cardiovasc Surg 2003;125:809-20
7. SoS Investigators. Coronary artery bypass surgery versus percutaneous coronary intervention with stent implantation in patients with multivessel coronary artery disease (the Stent or Surgery trial): a randomized controlled trial. Lancet. 2002 Sep 28;360(9338):965-70.
8. Serruys PW, Unger F, Sousa EJ, Jatene A, Bonnier HJ, Schönberger JP, Buller N, Bonser R, Van Den Brand MJ, Van Herwerden LA, Morel MM, Van Hout BA. Comparison of coronary-artery bypass surgery and stenting for the treatment of multivessel disease. N Engl J Med 2001;344:1117-24.
9. Hill R, Bagust A, Bakhai A, Dickson R, Dundar Y, Haycox A, et al. Coronary artery stents: a rapid systematic review and economic evaluation. Health Technol Assess 2004; 8 (35)
10. Kim SW, Hong MK, Lee CW, Kim JJ, Park SW, Park SJ. Multivessel coronary stenting versus bypass surgery in patients with multivessel coronary artery disease and normal left ventricular function: immediate and 2-year long-term follow-up. Am Heart J 139(4):638-642, 2000
11. Rodriguez A, Alemparte RM, Baldi J, Navia J, Delacasa A, Vogel D, Oliveri R, Pereira FC, Bernardi V, O'Neill W, Palacios FI. Coronary stenting versus coronary bypass surgery in patients with multiple vessel disease and significant proximal LAD stenosis: results from the ERACI II study. Heart 2003;89:184–188
12. Bhatt DL, Topol EJ. Debate: PCI or CABG for multivessel disease? Viewpoint: No clear winner in an unfair fight. Curr Control Trials Cardiovasc Med 2001,2:260-262

13. Schühlen H, Kastrati A, Dirschinger J, Hausleiter J, Elezi S, Wehinger A, Pache J, Hadamitzky M, Schömig A. Intracoronary Stenting and Risk for Major Adverse Cardiac Events During the First Month. Circulation 1998;98:104-111

14. Kastrati A, Schömig A, Elezi S, Dirschinger J, Mehilli J, Schühlen h, Blasini H, Neumann FJ. 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;100:1285-1290

15. Orlic D, Bonizzoni E, Stankovic G, Airoldi F, Chieffo A, Corvaja N, Sangiorgi G, Ferraro M, Briguori C, Montorfano M, Carlino M, Colombo A. Treatment of multivessel coronary artery disease with sirolimus-eluting stent implantation: immediate and mid-term results. J Am Coll Cardiol 2004;43:1154 –60

16. Prashant T. Upasani: Multivessel Angioplasty. The Internet Journal of Cardiology. 2003. Volume 2 Number 1.

17. Holmes DR. Risk stratification and interventional cardiology: Robert L.Frye Lecture. Mayo Clin Proc 2003;78:1507-1518

18. Morice MC, Serruys PW, Sousa EJ, Fajadet J, Hayashi EB, Perin M, Colombo A, Schuler G, Barragan P, Guagliumi G, Molnàr F, Falotico R. A randomized comparison of a sirolimus-eluting stent with a standard stent for coronary revascularization. N Engl J Med 2002;346:1773-80.

19. Cutlip DE, Chhabra AG, Baim DS, Chauhan MS, Marulkar S, Massaro J, Bakhai A, Cohen DJ, Kuntz RE, Ho KK. Beyond restenosis. Five-year clinical outcomes from second-generation coronary stent trials. Circulation 2004;110:1226-1230.

20. Rankin JM, Spinelli JJ, Carere RG, Ricci DR, Penn IM, Hilton DJ, Henderson MA, Hayden RI, Buller CE. Improved clinical outcome after widespread use of coronary-artery stenting in Canada. N Engl J Med 1999;341:1957-65.

21. Beers MH, Berkow R. The Merck Manual of Diagnosis and Therapy. Factors affecting drug response. Sec. 22, Ch. 301. Seventeenth, Centennial Edition. Available from URL: http://www.merck.com/mrkshared/mmanual/sections.jsp

22. Oksuzyan A, Demirchyan A, Thompson ME. Validation study of the patient follow-up questionnaire and the official pre-publication SF-36 Armenian version at the Nork Marash Medical Center. Yerevan, Armenia: Center for Health Services Research and Development, March 2003.

Appendix 1. Questionnaire 1. Medical record review

ID # _____ Name _____

1. Age ____ years **2. Gender** 0.□ Male 1.□ Female	**3. Valvular HD** 0.□ No 1.□ Yes 3a. Specify _____
4. Stable angina 0.□ No 1.□ Yes	**5. Unstable angina** 0.□ No 1.□ Yes
6. Cong. Heart Failure (NYHA) 0.□ No 1. □ Yes **6a.** 1.□ 0 2.□ I 3.□ II 4.□ III 5.□ IV	**7. Previous myocardial infarction 0.□ No 1.□ Yes** **7.1. Acute MI** 0.□ No 1.□ Yes
8. Previous cardiac intervention (besides the last one) 0.□ No 1.□ Yes	**9. Previous cardiac surgery** 0.□ No 1.□ Yes
10. Hypertension 0.□ No 1.□ Yes	**11. Diabetes mellitus** 0.□ No 1.□ Yes
12. Ejection fraction _____% 1.□ Good (>=50%) 2.□ Impaired (25-49%)	**13. Date of procedure** _ _ / _ _ / _ _
14. Number of diseased coronary vessels 1.□Single 2.□Two 3.□Three vessel a. □ Left anterior descending b. □ Left circumflex c. □ Right coronary	**15. Type of stent used & Vessel size (mm)** **a.** _____ _____ **b.** _____ _____ **c.** _____ _____ **d.** _____ _____ **16. Total number of stents** _____
17. Complete revascularization 0.□ No 1.□ Yes	**18. Medications prescribed after stent placement** a. Aspirin 0.□ No 1.□ Yes b. β-blocker 0.□ No 1.□ Yes c. ACEI 0.□ No 1.□ Yes
19. Acute outcome (In-hospital event) 0.□ No 1.□ Yes	
19_a. Death 0.□ No 1.□ Yes	**19_b.Nonfatal myocardial infarction** 0.□ No 1.□ Yes
19_c. Emergency CABG 0.□ No 1.□ Yes	**19_d. Other event** 0.□ No 1.□ Yes **19_d_a. Specify**_____

Diagnostic test performed during the follow-up period:

20. Coronarography (date and result)

1. _____
2. _____
3. _____

21. Treadmill test (date and result)

1. _____
2. _____
3. _____

Late outcome (follow-up result)

		Date*
20. Death	0.□ No 1.□ Yes	_ _/_ _/_ _
21. Nonfatal MI	0.□ No 1.□ Yes	_ _/_ _/_ _

22. Repeat revascularization_stent 0.□ No 1.□ Yes _ _/_ _/_ _

23. Repeat revascularization_CABG 0.□ No 1.□ Yes _ _/_ _/_ _

24. Need for target Lesion revascularization 0.□ No 1.□ Yes _ _/_ _/_ _

25. Angina recurrence 0.□ No 1.□ Yes _ _/_ _/_ _

25_a. With objective data 0.□ No 1.□ Yes

26. Any event** 0.□ No 1.□ Yes _ _/_ _/_ _

27. Date of last visit - _ _/_ _/_ _

***For all *Date* write the date of the event (if Yes), contact date/last follow-up visit date (if No)**
****For *any event* (if Yes) write the date of the earliest event from Q № 20, 21, 22, 23.**

Appendix 2. Questionnaire 2. Telephone interview

ՀԱՐՑԱԹԵՐԹԻԿ 2. Հեռախոսային հարցազրույց

Ամսաթիվ ____/_____/_____ **Տարբերակման համար** _____

Հարգելի պարոն/տիկին _____ (համաձայնագիր)

1. Ստենտավորումից հետո երբևէ ունեցե՞լ եք սեղմող, այրող բնույթի ցավեր կրծքավանդակում:

0. ☐ Ոչ ⟶ **Անցնել հարց 5:**
1. ☐ Այո ⟶ 1.1. Սկսվելու ամսաթիվը _____

2.Եթե այո, արդյոք այդ ցավերը նմա՞ն են եղել մինչ ստենտավորումն ունեցած ցավերին:

0. ☐ Ոչ 1. ☐ Այո 88. ☐ Դժվարանում եմ պատասխանել

3. Սովորաբար ինչքա՞ն են տևում այդ ցավերը:

0. ☐ Մի քանի վայրկյան (<30 վրկ.)
1. ☐ Մինչև 30 րոպե
2. ☐ 30 րոպեից ավելի

4. Եթե դիմել եք սրտաբանի, ապա ի՞նչ խորհուրդ է տրվել՝

4_a.1.☐ՆՄԲԿ սրտաբան 4_a.2.☐ Այլ սրտաբան

Խորհուրդ՝	**տրված (a)**	**կատարված (b)**
1. Դեղորայքային բուժում	0. ☐ Ոչ 1.☐ Այո	0. ☐ Ոչ 1.☐ Այո
2. Տրեդմիլ տեստ	0. ☐ Ոչ 1.☐ Այո	0. ☐ Ոչ 1.☐ Այո
3. Կորոնարոգրաֆիա	0. ☐ Ոչ 1.☐ Այո	0. ☐ Ոչ 1.☐ Այո

5. Ստենտավորումից ի վեր պառկե՞լ եք հիվանդանոց սրտի հիվանդության պատճառով:

☐ 0. Ոչ
☐ 1. Այո ↘

Հիվանդանոցի անունը	**պառկելու ամիսը, տարին**	**պառկելու պատճառը**
1.		
2.		

6. Դուք ծխու՞մ եք ներկայումս:

0. ☐ Ոչ
1. ☐ Այո ⟶ **Օրեկան քանի՞ սիգարետ *(միջինում)*** _____

7. Դուք ծխե՞լ եք նախքան ստենտավորման միջամտությունը:

0. ☐ Ոչ
1. ☐ Այո ⟶ **Քանի՞ տարի** _____

8. Ներկայումս ինչպես կգնահատեի՞ք Ձեր Ֆիզիկական ակտիվությունը:

0. ☐ Նստակյաց
1. ☐ Միջին
2. ☐ Ակտիվ

9. Երբևէ որոշվե՞լ է Ձեր արյան խոլեստերինի մակարդակը:

0. ☐ Ոչ
1. ☐ Այո ⟶ Ե՞րբ վերջին անգամ _____
88. ☐ Չեմ հիշում/Չգիտեմ

10. Եթե այո, երբևէ Ձեզ մոտ հայտնաբերվե՞լ է խոլեստերինի բարձր մակարդակ արյան մեջ:

0. ☐ Ոչ 1. ☐ Այո 88. ☐ Չեմ հիշում/Չգիտեմ

11. Դուք ՆՄԲԿ-ում ստացե՞լ եք խորհրդատվություն, թե ինչպիսի դիետա պետք է պահպանել:

0. ☐ Ոչ 1. ☐ Այո 88. ☐ Չեմ հիշում/Չգիտեմ

12. Եթե այո, որքանո՞վ եք հետևում նշանակված դիետային:

0. ☐ Բոլորովին չեմ հետևում
1. ☐ Մասամբ հետևում եմ
2. ☐ Լիովին հետևում եմ

13. Ձեր արյունակից հարազատների շրջանում եղե՞լ են անձինք, ովքեր ունեցել են ՍԻՀ, ՍԻ, հանկարծամահություն:

0. ☐ Ոչ
1. ☐ Այո
88. ☐ Չեմ հիշում/Չգիտեմ

14. Խնդրում ենք թվել, թե ինչ դեղորայք են Ձեզ նշանակել կենտրոնում Ձեր վերջին այցի ժամանակ և որոնք եք դուք ընդունում.

Դեղորայք	Նշանակված (a)	Ընդունվող (b)
1. Aspirin	0. ☐ Ոչ 1.☐ Այո	0. ☐ Ոչ 1.☐ Այո 2. ☐ Հանված ԲԽ
2. BB	0. ☐ Ոչ 1.☐ Այո	0. ☐ Ոչ 1.☐ Այո 2. ☐ Հանված ԲԽ
3. ACI	0. ☐ Ոչ 1.☐ Այո	0. ☐ Ոչ 1.☐ Այո 2. ☐ Հանված ԲԽ
4. LL	0. ☐ Ոչ 1.☐ Այո	0. ☐ Ոչ 1.☐ Այո 2. ☐ Հանված ԲԽ
4_2. Other	0. ☐ Ոչ 1.☐ Այո	0. ☐ Ոչ 1.☐ Այո 2. ☐ Հանված ԲԽ

15. Ինչպե՞ս կգնահատեիք Ձեր առողջությունն ընդհանուր առմամբ:

1. ☐ Գերազանց
2. ☐ Շատ լավ
3. ☐ Լավ
4. ☐ Ոչ այնքան լավ
5. ☐ Վատ

16.Ինչպե՞ս կգնահատեիք Ձեր առողջությունն **<u>այժմ՝ համեմատած նախքան ստենտավորումը եղածի հետ:</u>**

1. ☐ Շատ ավելի լավ այժմ, քան նախքան միջամտությունը
2. ☐ Որոշ չափով ավելի լավ այժմ, քան նախքան միջամտությունը
3. ☐ Այժմ գրեթե նույնը, քան նախքան միջամտությունը
4. ☐ Որոշ չափով ավելի վատ այժմ, քան նախքան միջամտությունը
5. ☐ Շատ ավելի վատ այժմ, քան նախքան միջամտությունը

Շնորհակալություն, որ պատասխանեցիք մեր հարցերին: