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# Impact of Admission, Fasting Glucose and HbA1c Levels on in-stent Restenosis in The Patients Treated with Primary Percutaneous Coronary Intervention in 5-Year Follow-up

## *Beş Yıllık Izlemde HbA1c, Başvuru ve Açlık Kan Şekeri Düzeylerinin Primer Perkütan Koroner Girişim Yapılan Hastalarda in-Stent Restenozuna Etkisi*

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### Abstract

**Aim:** Despite advances in-stent technology, in-stent restenosis (ISR) is still a major problem following percutaneous coronary intervention (PCI) and its reasons have not been fully revealed. In the presented study, we investigated the effect of admission blood glucose (ABG), fasting blood glucose (FBG) and glycated hemoglobin A1c (HbA1c) levels on coronary ISR patients with ST-elevation myocardial infarction (STEMI) who underwent primary PCI in five-year follow-up.

**Methods:** From 2.900 patients who underwent coronary stent implantation for STEMI from January 2008 through December 2012 were retrospectively analyzed through the hospital digital recording system. Of these, 264 patients who underwent control coronary angiography during the five-year follow-up were included in the study. Patients were divided into two main group ISR and non-ISR; were divided into two subgroups diabetic and non-diabetic groups were compared with HbA1c, ABG, FBG and angiographic parameters.

**Results:** There were 127 patients in the ISR group (diabetic: 36 non-diabetic: 91) and 137 patients in the non-ISR group (diabetic: 43 non-diabetic: 94). Regardless of the patients diabetes status, no significant difference was found between the groups with and without ISR in terms of HbA1c, FBG and ABG. A significant relationship was found between the baseline HbA1c value and having ISR only in the diabetic subgroup (p=0.01).

**Conclusion:** This study results showed that in diabetic STEMI patients who underwent primary PCI, higher HbA1c levels were associated with higher ISR rates, but not with FBG and ABG levels.

**Keywords:** ST elevation myocardial infarction, blood glucose, glycated hemoglobin A1c, percutaneous coronary intervention, coronary angiography, coronary restenosis, diabetes mellitus

### Öz

**Amaç:** Stent teknolojisindeki ilerlemelere rağmen perkütan koroner girişimi (PKG) takiben gelişen in-stent restenozu (ISR) halen önemli bir sorundur ve nedenleri tam olarak ortaya konulamamıştır. Sunulan çalışmada primer PKG uygulanmış ST-segment yükselmeli akut miyokard enfarktüsü (STEMI) hastalarında başvuru kan şekeri (BKŞ), açlık kan şekeri (AKŞ) ve HbA1c düzeylerinin 5 yıllık izlemde koroner ISR üzerine etkisi analiz edildi.

**Yöntemler:** Ocak 2008-Aralık 2012 tarihleri arasında STEMI nedeniyle koroner stent implantasyonu uygulanan 2.900 hasta, hastane dijital kayıt sisteminden geriye dönük olarak incelendi. Bunlardan beş yıllık takipte kontrol koroner anjiyografisi yapılan 264 hasta çalışmamıza dahil edildi. Hastalar ana grup olarak ISR ve non-ISR; alt grup olarak ise diyabetik ve diyabetik olmayanlar olarak ayrıldı ve gruplar HbA1c, BKŞ, AKŞ ile birlikte anjiyografik parametreler açılarından karşılaştırıldı.

**Bulgular:** ISR grubunda toplam 127 hasta (diyabetik: 36 non-diyabetik 91) ve non-ISR grubunda toplam 137 hasta (diyabetik: 43 non-diyabetik: 94) mevcuttu. Hastaların diyabetik olup olmamasına bakılmaksızın, ISR olan ve olmayan gruplar arasında AKŞ, BKŞ ve HbA1c değerleri açısından anlamlı fark saptanmadı. Sadece diyabetik alt grupta HbA1c değeri ile ISR arasında anlamlı ilişki saptandı (p=0,01).

**Sonuç:** Çalışma sonuçlarımız, primer PKG uygulanan diyabetik STEMI hastalarında yüksek HbA1c düzeylerinin daha yüksek ISR oranlarıyla ilişkili olduğunu, fakat BKŞ ve AKŞ düzeyleri ile ilişkili olmadığını gösterdi.

**Anahtar Sözcükler:** ST yükselmeli miyokard enfarktüsü, kan glukozu, glikozile hemoglobin A1c, perkütan koroner girişim, koroner anjiyografi, koroner restenoz, diabetes mellitus

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## Introduction

Restenosis is defined as a decrease in the luminal diameter after the percutaneous coronary intervention (PCI), regarding if the stent is implanted or not. In-stent restenosis (ISR) is often defined as the restenosis anywhere between 5 mm from the proximal or distal edges of the stent associated with the loss of more than 50% of the diameter of the vessel which had been successfully treated (1-2). The most important limitations of the successful treatment of stenotic coronary artery through PCI are acute or late stent thrombosis and ISR.

Despite significant advances in interventional techniques such as new-generation bare-metal stents (BMS), drug-eluting stents (DES), drug-coated balloons, and drug therapies, ISR remains a significant problem in interventional cardiology, especially in diabetic patients (3-6). Diabetes mellitus (DM) is a critical patient-related cause in the pathogenesis of ISR (7). Glycosylated hemoglobin is a biomarker for the time-integrated average blood glucose and is assessed clinically with glycated hemoglobin A1c (HbA1c). HbA1c is used increasingly and more commonly for screening during the management of diabetes. HbA1c is more closely related to the total risk of complications in DM than other (single or intermittent) measurements of blood glucose level (8). HbA1c provides a simple method to assess a patient's DM status and prognosis of coronary stent implantation in terms of ISR and other cardiovascular outcomes (9,10).

In the last century, although many studies have been conducted on ISR, but it has not been clearly revealed which patients are susceptible to ISR both in diabetic and non-diabetic patients. This study aimed to evaluate the relationship between ISR and HbA1c, admission blood glucose (ABG), and fasting blood glucose (FBG) in diabetic and non-diabetic patients.

## Methods

### Patient Population

The study protocol was in accordance with the Declaration of Helsinki and approved by the local Dr. Siyami Ersek Hospital) Ethics Committee (13.08.2013 date and 2. number decision). We accessed hospital digital records retrospectively for the patients who underwent coronary stent implantation for ST-segment elevation myocardial infarction (STEMI) from January 2008 through December 2012 from a total of 2.900 patients. Among these patients, 2.636 patients who did not have control coronary angiography during the five-year follow-up were excluded. In those patients, we included 264 patients whose control coronary angiography was performed because of a stable angina pectoris, unstable angina pectoris, non-STEMI, and STEMI during the five-year follow-up. ISR was detected in 127 patients, and no-ISR was detected in 137 patients.

Those who had a history of diabetes and used a restrictive diet, oral hypoglycemic medication, or insulin or those with an FBG level of ≥126 mg/dL on two occasions during hospitalization or an HbA1c level ≥6.5% were evaluated as diabetic. DM was detected in 79 patients (HbA1c ≥6.5%); 185 patients were non-diabetic (HbA1c <6.5%).

The patients' clinical and demographic characteristics were noted, including age, gender, and histories of DM, arterial hypertension, hyperlipidemia, coronary artery disease (CAD), tobacco use, and medications.

### Laboratory Tests

For each patient, FBG, ABG, HbA1c, low-density lipoprotein (LDL) cholesterol, high-density lipoprotein (HDL) cholesterol, triglycerides, total cholesterol, white blood cell count (WBC), hemoglobin, platelet count, and peak creatine kinase MB isoenzyme (CKMB) were measured in the first 24 hours of hospital admission. HbA1c was examined by immuno-turbidimetric method (Modular P800i, Roche, Germany) with the Tina-quant HgA1c II kit.

### Angiographic Parameters

Current practice guidelines were followed for coronary interventions, and the data were recorded in digital storage for quantitative analysis. Access site for PCI was femoral with the Judkins technique. Two experienced interventional cardiologists estimated the degree of coronary stenosis visually. Significant stenosis was defined as a luminal narrowing of >50% in a major subepicardial vessel (left anterior descending, left circumflex, or right coronary artery). After stent placement, clopidogrel was used for at least one year, and aspirin was used indefinitely. All treatments were given following the European Society of Cardiology guidelines. The patient adherence to medical therapy was standardized. Coronary angiography was performed secondarily during routine clinical follow-up in the patients with stable angina pectoris, unstable angina pectoris, non-STEMI, and STEMI. The Judkins technique was used to record control coronary angiograms. Two independent cardiologists who were blinded to the patients' data interpreted the angiograms. In coronary angiography, a narrowing of >50% in 5-mm proximal and the distal of the stent edge in an otherwise normal diameter was accepted as stent restenosis.

### Statistical Analysis

Statistical Package for the Social Sciences (SPSS Windows version 20.0, IBM Corp, USA) was used in all analyses. Quantitative variables with a normal distribution were given as the mean ± standard deviation, and those with non-normal distribution were given as the median (minimum and maximum). Chi-square test and Fisher exact test were used for categorical variables to compare the groups. Mann-Whitney U test was used to compare the instruments of the two groups that were not normally distributed and the normal distributions were compared using the student's t-test. A p-value of <0.05 was considered statistically significant.

## Results

Of the 264 patients in this study, 127 patients were diagnosed with ISR over 50% stenosis. There were 79 diabetic patients: 36 in the ISR group and 43 non-ISR group. The demographic characteristics of the patients and the risk factors were given in Table 1. Their baseline clinical characteristics were similar except they are more likely to be male in in ISR group and history of coronary artery disease is more common in non-ISR group. The vessels implanted with a stent in the primary PCI, the number of vessels involved, and the restenosis treatment were shown in Table 2. The average stent diameter and length were 3.0±0.42 and 20.0±6.1 in the ISR group and 2.98±0.75 and 17.7±6.0 in the non-ISR group, respectively. The two groups did not differ significantly in terms of target vessel, lesion type classified according to American College of Cardiology/American Heart Association, and implanted stent type, size except length. Of the patients who developed ISR, 63 underwent repeat PCI, 46 underwent coronary bypass operation, and 18 were followed up with drug treatment.

The laboratory parameters of the patients were detailed in Table 3. For the whole patient group, the mean FBG, ABG, and HbA1c values were 121±5, 171±85, and 6.65±1.69 in the ISR group and 118±41, 169±83, and 6.39±1.29 in the non-ISR groups, respectively. The difference between the ISR and non-ISR groups was not statistically significant (p>0.05). When these parameters were examined in the diabetic subgroup, there was no significant difference between the ISR and non-ISR groups regarding the FBG (164±82 vs.152±53, p=0.44) and ABG (245±100 vs. 229±105, p=0.53). However, a significant difference was found between the ISR and non-ISR groups regarding the HbA1c values (7.47±1.57 vs. 8.60±1.82, p=0.01) (Figure 1). The differences between the ISR and non-ISR groups in the diabetic patients regarding the demographic, angiographic, and laboratory parameters were given in Table 4.

**Table 1. Baseline demographic characteristics of the study population**

| | ISR (n=127) | Non-ISR (n=137) | p |
|---|---|---|---|
| Age (years), mean ± SD | 56.1±10.2 | 56.8±10.8 | 0.54 |
| Gender male, n (%) | 113 (89%) | 69 (50.4%) | 0.01 |
| Female, n (%) | 14 (11%) | 68 (49.6%) | 0.01 |
| Hypertension, n (%) | 64 (50.4%) | 57 (41.6%) | 0.37 |
| Diabetes mellitus, n (%) | 36 (28.3%) | 43 (31.4%) | 0.59 |
| Insulin user, n (%) | 2 (5.5%) | 17 (39.5%) | 0.01 |
| Oral anti-diabetic user, n (%) | 34 (94.4%) | 26 (60.4%) | 0.13 |
| Hyperlipidemia, n (%) | 54 (42.5%) | 39 (28.5%) | 0.18 |
| Smoker, n (%) | 71 (55.9%) | 63 (46%) | 0.31 |
| History of coronary artery disease, n (%) | 19 (15%) | 79 (57.7%) | 0.01 |

SD: Standard deviation, ISR: In-stent restenosis

**Table 2. Baseline angiographic parameters of the study population and treatment modality of ISR group**

| | ISR (n=127) | Non-ISR (n=137) | p |
|---|---|---|---|
| Culprit artery | | | |
| LAD, n (%) | 66 (51.9%) | 73 (53.2%) | |
| CX, n (%) | 18 (14.1%) | 29 (21.1%) | 0.18 |
| RCA, n (%) | 43 (33.8%) | 35 (25.5%) | |
| Number of diseased vessels, mean±SD | 1.80±0.79 | 1.68±0.80 | 0.23 |
| Stent diameter (mm), mean±SD | 3.0±0.42 | 2.98±0.75 | 0.72 |
| Stent length (mm), mean ± SD | 20.0±6.1 | 17.7±6.0 | 0.01 |
| Treatment of stent restenosis | | | |
| Medical, n (%) | 18 (14.1%) | - | - |
| PCI, n (%) | 63 (49.6%) | - | - |
| CABG, n (%) | 46 (36.2%) | - | - |

LAD: Left anterior descending artery, CX: Circumflex artery, RCA: Right coronary artery, CABG: Coronary artery by-pass grafting, SD: Standard deviation, ISR: In-stent restenosis

**Table 3. Admission laboratory parameters of study population**

| | ISR (n=127) Mean ± SD | Non-ISR (n=137) Mean ± SD | p |
|---|---|---|---|
| Hemoglobin (mg/dL) | 14.1±1.4 | 14.0±1.6 | 0.21 |
| Platelet (103/μL) | 295±80 | 235±75 | 0.25 |
| WBC (103/μL) | 12.1±3.9 | 11.9±4.6 | 0.79 |
| Creatinine (mg/dL) | 0.89±0.31 | 0.88±0.22 | 0.65 |
| Peak-CKMB (IU/L) | 160±120 | 195±140 | 0.05 |
| Total cholesterol (mg/dL) | 189±53 | 184±43 | 0.40 |
| LDL cholesterol (mg/dL) | 116±41 | 110±36 | 0.20 |
| HDL cholesterol (mg/dL) | 37±9 | 39±10 | 0.09 |
| Triglyceride (mg/dL) | 130±108 | 141±100 | 0.77 |
| Fasting blood glucose (mg/dL) | 121±5 | 118±41 | 0.61 |
| Admission blood glucose (mg/dL) | 171±85 | 169±83 | 0,82 |
| HbA1c (%) | 6.65±1.69 | 6.39±1.29 | 0.17 |

SD: Standard deviation, WBC: White blood cell, CKMB: peak Creatine kinase MB isoenzyme, LDL: Low-density lipoprotein, HDL: High-density lipoprotein, HbA1c: Glycated hemoglobin A1c, ISR: In-stent restenosis

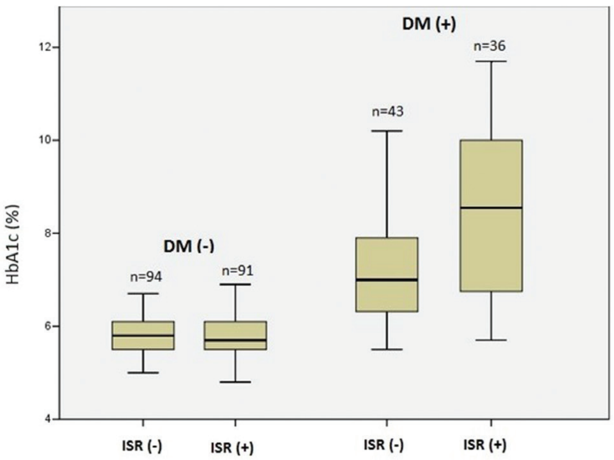


**Figure 1.** Comparison of in-stent restenosis with HbA1c level in diabetic patients and non-diabetic group

*ISR: In-stent restenosis, DM: Diabetes mellitus, HbA1c: Glycated hemoglobin A1c*

**Table 4. Demographic characteristics and laboratory and angiographic parameters in the diabetic sub-group**

| | ISR (n=36) | Non-ISR (n=43) | p |
|---|---|---|---|
| Age (years) mean ± SD | 55.8±11.3 | 58.1±8.8 | 0.33 |
| Gender male (n) (%) | 32 (88.8%) | 18 (41.8%) | 0.01 |
| Female (n) (%) | 4 (11.1%) | 25(58.1%) | 0.01 |
| Hypertension (n) (%) | 25 (69.4%) | 22 (51.1%) | 0.20 |
| Hyperlipidemia (n) (%) | 20 (55.5%) | 15 (34.8%) | 0.06 |
| History of coronary artery disease (n) (%) | 6 (16.6%) | 30 (69.7%) | 0.01 |
| Hemoglobin (mg/dL) mean±SD | 13.9±1.4 | 13.7±1.9 | 0.61 |
| WBC (103/µL) mean ± SD | 12.1±3.9 | 11.9±4.6 | 0.79 |
| Creatinine (mg/dL) mean ± SD | 0.89±0.31 | 0.88±0.22 | 0.46 |
| Peak CKMB (IU/L) mean ± SD | 115±84 | 205±150 | 0.02 |
| Total cholesterol (mg/dL) mean ± SD | 192±48 | 189±49 | 0.79 |
| LDL cholesterol (mg/dL) mean ± SD | 112±44 | 115±39 | 0.71 |
| HDL cholesterol (mg/dL) mean ± SD | 36±10 | 38±9 | 0.31 |
| Triglyceride (mg/dL) mean ± SD | 151±109 | 159±121 | 0.48 |
| Fasting blood glucose (mg/dL) mean ± SD | 164±82 | 152±53 | 0.44 |
| Admission blood glucose (mg/dL) mean ± SD | 245±100 | 229±105 | 0,53 |
| HbA1c (%) mean ± SD | 8.60±1.82 | 7.47±1.57 | 0.01 |
| Stent diameter (mm) mean ± SD | 3.02±0.32 | 2.96±0.78 | 0.69 |
| Stent length (mm) mean ± SD | 20.41±5.48 | 18.53±5.69 | 0.15 |

SD: Standard deviation, WBC: White blood cell count, CKMB: peak creatine kinase MB isoenzyme, LDL: Low-density lipoprotein, HDL: High-density lipoprotein, HbA1c: Glycated hemoglobin A1c, ISR: In-stent restenosis

## Discussion

It is well known that DM is associated with an increased of cardiovascular mortality and plays a main role in ISR development (11). Additionaly, it is shown that ISR was an independent risk factor for mortality (12). The results of this study evaluated the effects of FBG, ABG, and HbA1c on the long-term ISR rate in both diabetic and non-diabetic patients who underwent primary PCI. Our study shows that admission HbA1c levels are associated with higher ISR rates in a diabetic STEMI population treated with primary PCI. Our findings are supported with several previous studies reporting increased rates of ISR following PCI in uncontrolled diabetic patients (13-15).

Measurement of HbA1c levels with ABG and FBG levels in non-diabetic patients may improve risk assessment in patients presenting with acute STEMI. Our study showed no association between these parameters and ISR rates in non-diabetic patients. Naito et al. (13) investigated the effects of ABG and HbA1c on the long-term PCI outcomes in 452 non-diabetic patients presenting with acute coronary syndrome (ACS). They showed that the ABG and HbA1c values were independently correlated with the clinical outcomes in non-diabetic ACS patients treated with PCI (13). This association is supported by some other works (16,17). Our investigation could not demonstrate this association. The reason of this can be low number of study patients in this study and glucose variability.

In an other study high HbA1c levels were suggested to predict cardiovascular disease frequency and mortality in non-diabetic patients, independent of FBG (18). Pai et al. (19) showed in their study that increasing HbA1c levels increases the risk of coronary artery disease in patients with diabetes and non-diabetic patients. In a meta-analysis by Cavero-Redondo et al. (10), a relationship was found between HbA1c levels and mortality and cardiovascular outcomes in both diabetic and non-diabetic patients. In their analysis, all-cause mortality was higher when HbA1c levels were over 6% and 8% in non-diabetic and diabetic patients, respectively (10).

The development of ISR is a complex and multifactorial process; there are patient-, vessel-, and procedure-related factors involved (20). Among the identified factors associated with the patient, DM was considered one of the high-risk clinical predictors for ISR, which was found to be 30-50% following BMS implantations (21). Although the rate of ISR in DES was found to be lower than that in BMS, it was higher in diabetic patients compared to non-diabetic patients (22,23). In a meta-analysis, an association was found between HbA1c level and cardiovascular outcomes in diabetic patients after PCI (24). Anatomically, both lesion length and lesion diameter are predictors of ISR. Generally, the length of the lesion and the narrow

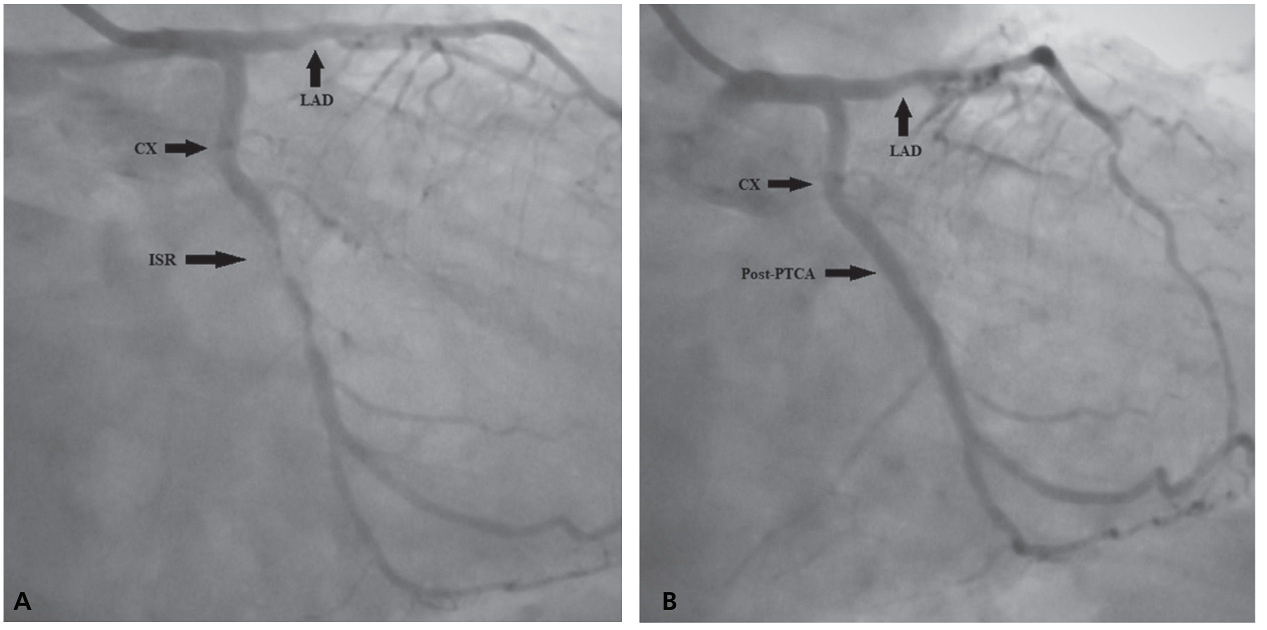


**Figure 2.** A) In-stent critical lesion in CX coronary artery, B) After treatment with PTCA in stenotic CX coronary artery
Example of ISR case report: 65 years old patient presented with chest pain. He had a history of hypertension, diabetes mellitus and primary PCI to CX coronary artery due to acute inferior MI two years ago. His HbA1c, ABG and FBG levels were 10.1%, 187 mg/dL, 150 mg/dL respectively during admission. A control CAG was performed with the diagnosis of non-STEMI. The control CAG revealed 95% ISR in CX coronary artery. Percutan transluminal coronary angioplasty is performed into restenotic segment and full openness was achieved.
*LAD: Left anterior descending artery, CX: Circumflex artery, PTCA: Percutaneous transluminal coronary angioplasty*

diameters have been shown to increase the incidence of ISR (22). In the diabetic subgroup in our study, no significant difference was found between the ISR and non-ISR groups in terms of stent length and diameter. Since our hospital is a tertiary center for cardiovascular diseases and all angiographies are performed by two experienced cardiologists, the factors related to ISR procedures were standardized.

HbA1c is an important marker revealing the long-term glycemic follow-up of diabetic patients. Increased HbA1c levels are associated with microvascular and macrovascular complications. In our study, the reasons for not finding a significant relationship between the ISR and ABG or FBG, as opposed to HbA1c, could be that HbA1c does not require fasting, its biological variability and irregularity before analysis is less, and it is not affected by acute changes in blood glucose levels. In previous studies, microvascular and macrovascular symptoms of diabetes were observed above the limit value of 6.5%; an HbA1c cut-off value of ≥6.5% was established for the diagnosis of DM in the last report of the American Diabetes Association (9). For this reason, we took the HbA1c cut-off as 6.5% in this study.

The clinical manifestation of ISR commonly includes recurring angina symptoms or ACS, and it may lead to a re-intervention either with coronary artery bypass or repeat PCI (25). We presented an example case about ISR (Figure 2A-B)

### Study Limitations

This study analyzed the data derived from a single center. An important limitation of our study is the low number of study patients. In addition, since our study was retrospective, the patients' glycemic control during their long follow-up period could not be corroborated. Although the restenosis rates of DESs were found to be lower in diabetic patients in recent studies, a BMS was applied in our study. Although the HbA1c level was affected in the patients with low hemoglobin levels and hemoglobinopathy, the patients with anemia were excluded from our study, and the measuring device we used did not interact with abnormal hemoglobin.

## Conclusion

HbA1c is strong independent predictor of ISR in patients with DM after coronary stent implantation. Our findings supported that strict diabetes control such as prescribing aggresive glucose lowering medication will reduce ISR rates in the subpopulation of DM patients. This relationship was not observed in non-diabetic patients. Extensive, randomized studies are needed to further demonstrate this relationship both in non-diabetic patients.

### Authorship Contributions

Concept: F.Ö.K., Design: F.Ö.K., M.E., Data Collection or Processing: F.Ö.K., Y.K., Analysis or Interpretation: B.G., Literature Search: F.Ö.K., Writing: F.Ö.K., Y.K.

**Conflict of Interest:** No conflict of interest was declared by the authors.

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