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ARAŞTIRMA / RESEARCH

Comparison of the early and long-term results of aortic-coronary bypass surgery and percutaneous coronary intervention with new generation drug-eluting stents in diabetic patients with acute coronary syndrome

Akut koroner sendromlu diyabetik hastalarda aort-koroner bypass cerrahisi ile yeni nesil ilaç salınımlı stentlerle uygulanan perkütan koroner girişimin erken ve uzun dönem sonuçlarının karşılaştırılması

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Abstract

Purpose: The aim of this study was to determine the difference between patients undergoing coronary artery bypass graft (CABG) and percutaneous coronary intervention (PCI) (with new generation drug-eluting stents) who had diabetes mellitus during the course of an acute coronary syndrome (ACS).
Materials and Methods: We carried out a retrospective evaluation of 405 diabetic patients admitted with an ACS during the period of 2 years in a single-center. Patients were followed for 5 years. All clinical incidents, such as death, cardiac death, myocardial infarction, stroke, revascularization, and stent thrombosis were recorded
Results: We examined 405 patients with diabetes out of 1643 patients with ACS. Of these, 183 (45.1%) were included in the PCI group and 222 (54.8%) were in the CABG group. During 5-years follow-up, primary endpoints including death, MI, and stroke were observed in 31 patients (16.9%) in the PCI group and in 33 patients (14.9%) in the CABG group. There was no difference between the two groups in terms of primary endpoints. All-cause mortality during 5-years was observed in 17 patients (9.8%) in the PCI, 20 (9.1%) in the CABG group.
Conclusion: There was no difference in all-cause mortality between the PCI and the CABG groups during 5-year follow-up. Repeated revascularization and myocardial infarction were higher in the PCI group and the stroke rates were higher in the CABG group.
Keywords:. coronary artery bypass graft, percutaneous coronary intervention, acute coronary syndrome

Öz

Amaç: Bu çalışmanın amacı diyabetik olgularda akut koroner sendrom (AKS) sırasında koroner arter baypas greft (KABG) ve Perkütan koroner girişim (PKG) (yeni nesil ilaç salınımlı stentlerle) uygulanmasının sonuçları arasındakifarkı belirlemekti.
Gereç ve Yöntem: Tek merkezde 2 yıllık dönemde AKS ile başvuran 405 diyabetik hastayı retrospektif olarak değerlendirdik. Hastalar 5 yıl boyunca takip edildi. Tüm nedenlerle ilişkili ölüm, kardiyak ölüm, miyokard enfarktüsü, inme, revaskülarizasyon ve stent trombozu gibi tüm klinik olaylar buna göre kaydedildi.
Bulgular: AKS'li 1643 hastanın 405'i diyabetli hastayı inceledik. Bunlardan 183'ü (% 45.1) PKG grubuna, 222'si (% 54.8) KABG grubuna dahil edildi. 5 yıllık takip sırasında, PKG grubunda 31 hastada (% 16.9) ve KABG grubunda 33 hastada (% 14.9) ölüm, MI ve inme gibi primer son noktalar gözlendi. İki grup arasında primer sonlanım noktaları arasında fark yoktu. 5 yıl boyunca tüm neden mortalite PKGI grubunda 17 hastada (% 9.8), KABG grubunda 20 hastada (% 9.1) gözlendi.
Sonuç: 5 yıllık takip sırasında PKG ve KABG grupları arasında tüm nedenlere bağlı mortalite açısından fark yoktu. Tekrarlanan revaskülarizasyon ve miyokard enfarktüsü, PKG grubunda KABG grubuna göre daha yüksekti. Buna karşılık inme oranları KABG grubunda daha yüksekti.

Anahtar kelimeler: akut koroner sendrom, koroner arter baypas greft, perkütan koroner girişim

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INTRODUCTION

The number of adult diabetic patients is expected to reach 642 million by 2040. Over the next 10 years, the mortality from diabetes will be significantly increased by 50%. It is believed that diabetes mellitus (DM) and its complications will likely lead to severe social and public health problems [1]. In general, DM occurs in 25-30% of patients with an Acute Coronary Syndrome (ACS), as well as in about 40% of patients undergoing coronary artery bypass grafting (CABG). In diabetic patients, ischemic heart disease is manifested to a greater extent by atherosclerosis, as well as significant increase in lipid-rich plaque. The probability of thrombosis is greater due to the fact that, the plagues are more prone to disruption [2-4].

Indications for myocardial revascularization in diabetic patients are similar to those in non-diabetic patients [5]. Angiographic studies have shown that the main coronary stenosis, many vessel obliterations and diffuse small vessel stenosis are common in these patients [6]. Therefore, management with either CABG or percutaneous coronary intervention (PCI) is of great importance in patients with DM. However, head to head comparison between PCI and CABG in randomized control studies does not reflect the real-life circumstances. Present study is conducted with the aim of identifying the clinical differences between PCI and CABG in the diabetic patients presenting with ACS in the real-world settings.

MATERIALS AND METHODS

This study evaluated the 405 consecutive diabetic patients with unstable angina pectoris (USAP) and non-ST segment elevation myocardial infarction (NSTEMI) who has undergone coronary revascularization therapy and has 2 parts. The first part was a retrospective evaluation and determination of the study population for 2 years. The second part was the prospective follow-up of the study population enrolled in the first part, by same physician during study period for 5 years at the Central Clinic Hospital and Azerbaijan Medical University Department of Cardiology. Study protocol was approved by the Institutional Review Board (Ethical Committee of Azerbaijan Medical University, 29.11.2019, No:10)

Patients were included study; if (I) they had admitted with an ACS (USAP or NSTEMI) [7] and had multi-vessel coronary artery disease (CAD) of at least two epicardial coronary arteries (stenosis ≥70%), (II) had DM, (III) had undergone to isolated PCI or CABG, and (IV) had a Syntax score (22-33). Patients with left main CAD, a history of previous cardiac surgery, previous PCI, cardiogenic shock, previous history of acute myocardial infarction (MI), new ST-Elevation Myocardial Infarction (STEMI) and elevated creatinine (> 2md/dl) were all excluded. USAP was defined as discomfort on the chest or acceleration of previous angina which occurred during the long-lasting exertion. ST-T changes was the supporting indicators of USAP. In that group of patient's normal troponin levels also supported the diagnosis of USAP.

Procedure

The clinical characteristics, laboratory parameters, and medical history were obtained from the patient charts recorded at the time of index hospitalization. Hypertension was defined as repeated systemic blood pressure measurements exceeding 140/90 mmHg or receiving antihypertensive medication [8]. DM was diagnosed as fasting blood glucose ≥126 mg/dL or blood glucose >200 mg/dL at any time or use of anti-glycemic medication [9]. Hypercholesterolemia was defined as a baseline total cholesterol level >200 mg/dL or current treatment with statins and/or lipid-lowering agents [10]. Current smokers were those with regular smoking within the previous 6 months. Syntax score was calculated according to the SYNTAX score algorithm [11].

Standard techniques were used for PCI and new-generation drug-eluting stents were implanted in the PCI group. Dual antiplatelet therapy with aspirin and clopidogrel was recommended for at least 12 months after stent implantation. All patients had evaluated with echocardiography by experienced echocardiographers according to European Association of Echocardiography/American Society of Echocardiography guidelines [12].

Follow-up and outcomes

Patients were followed for 30 days, 1 year, and 5 years. Follow-up information was collected either via phone contact or by face-to face hospital visits. All clinical events, such as death associated with all causes, cardiac death, MI, stroke, revascularization, and stent thrombosis were recorded accordingly. Both short-term (within 30 days) and long-term

(median 60 months) outcomes were evaluated. The primary endpoint of the study was short-term and long-term all-cause mortality. Secondary endpoints included major adverse cardiovascular events (MACE) that covered all-cause mortality, MI, stroke and repeat revascularization [11].

MI was defined as spontaneous, PCI related and CABG related. The indicators of MI were new or pathologic Q wave and/or serum troponin levels elevations during the 5 years follow up. We investigated all causes of death. Death was divided into two group: cardiac and non-cardiac causes. Cancer related death was defined as a separate group. Cerebrovascular events were defined as acute, lasting at least 24-hour with a permanent loss of function and brain damage. All cerebrovascular events were confirmed by a neurologist and imagining methods.

Statistical analysis

All analyses were performed by SPSS 18.0 package program. Continuous variables were expressed as mean, SD, minimum and maximum values and categorical variables as percentages. Student's t test and chi-square were used for statistical analysis. 30-Day follow-up were calculated as binary rates for short-term outcomes. Differences in long-term events were evaluated by Kaplan-Meier curve with the log-rank test. P value <0.05 was considered as statistically significant.

RESULTS

405 patients with DM, out of total 1643 patients with ACS were included in the study. PCI group included 183 (%45.1) patients, and 222 patients (%54.8) were in CABG group. The characteristics of the groups are shown in Table 1. There were no significant differences between the groups with regard to age, gender, prevalence of hypercholesterolemia, stroke, chronic kidney disease, left ventricular ejection fraction, current smoking and Syntax score. Patients with hypertension, peripheral vascular disease were significantly higher in CABG group than PCI group.

Left internal mammary artery (LIMA) was used in 95% of patients undergoing CABG. Median follow-up time was 60 months (interquartile range 48-72 months). The primary endpoint including death, MI, and stroke was observed in 31 patients (16.9%) in PCI group and in 33 patients (14.9%) in CABG group (p=0.582).

All-cause mortality within the first 30 days following the index revascularization, was similar between two groups (p=0.13). During that time, more strokes were observed in the CABG group than in the PCI group; 3 patients in the PCI group and 18 in the CABG group had a stroke (p=0.007). At 30 days, the primary endpoint was observed in 12(6.6%) patients in the PCI group, and in 8 patients (3.6%) in the CABG group (p=0.172). The repeated revascularization in the in the PCI group (3.3%) was higher than in the CABG group (1.1%) during that period (p=0.002) (Table 2).

All-cause mortality during 5-years follow-up was observed in 17 patients (%9.8) in the PCI group, and in 20 patients (%9.1) in the CABG group (p=0.989). However, MI percentage in the PCI group (9.3%) was higher than in the CABG group (4.2%) (p=0.034). Repeated revascularization was required in 18.4% of the PCI group and 10.8% in the CABG group (p = 0.012). A stroke occurred in 1.1% of patients in the PCI group and in 4.9% of patients in the CABG group (p = 0.05).

Table 1. Clinical characteristics of the groups

Patient Characteristics	PCI (n=183)	CABG (n=222)	P
Age, years (years)	56.1(± 8.5)	57.6(± 7.9)	P=0.071
Women n(%)	39(%21.3)	59(%26.6)	P=0.218
Hypercholesterolemia n(%)	(%62.8)	(%62.1)	P=0.623
Current smoker n(%)	(%24.1)	(%23.7)	P=0.898
Previous stroke n(%)	(%5.8)	(%6.9)	P=0.571
Hypertension n(%)	89(%34.1)	172(%65.9)	0.00016
Peripheral vascular disease n(%)	5(%2.7)	39(%17.6)	P=0.018
CKD (creatinine 150-200 mg/dl)	11(%6.0)	11(%5.0)	P=0,641
Left ventricular ejection fraction %	47.4	48.3	P=0.068
Syntax score	27.1	27.7	p=0.072

PCI: percutaneous coronary intervention, CABG: coronary artery bypass grafting surgery, and CKD: chronic kidney disease

Table 2. Estimates of major adverse cardiovascular and cerebrovascular events at 30 days and 12 months after the procedure

Event	30-Day follow-up, n (%)			5-year follow-up, n (%)		
	PCI	CABG	P value	PCI	CABG	P value
MACE	8(4.4)	7(3.2)	0.518	47(25.7)	52(23.5)	0.616
Death	9 (0.9)	17(1.6)	0.13	17 (9.8)	20 (9.1)	0.989
Myocardial infarction	3 (1.8)	4 (1.7)	0.82	18(9.3)	9(4.2)	0.034
Stroke	3 (0.4)	18 (1.9)	0.007	1.1	4.9	0.05
Repeat revascularization	6 (3.3)	3 (1.1)	0.002	18.4	10.8	0.012
Primary endpoint	12(6.6)	8(3.6)	0.172	31(16.9)	33(14.9)	0.582

PCI: percutaneous coronary intervention, CABG: coronary artery bypass grafting surgery, MACE: Major Adverse Cardiac Events

Seventy-one percent of all patients with ACS who underwent to PCI had suffered from MI. However, only 28.8% of patients in the CABG group had MI. The MACE percentage in the PCI group (25.7%) was higher than in the CABG group (23.5%), but it was not statistically significant (p = 0.616). (Table 2).

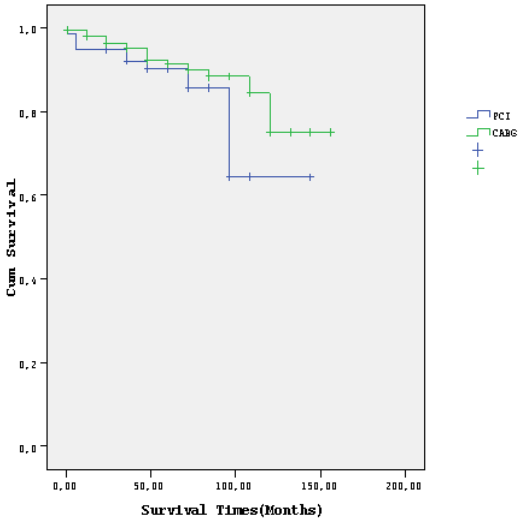

Figure 1. Kaplan-Meier Survival Analysis also shows that there is no difference between PCİ (in the use of new-generation drug eluting stents) and CABG during 5-years observation (p=0.353).

PCI: percutaneous coronary intervention, CABG: coronary artery bypass grafting surgery

When the long term mortality evaluated, there were only 16 deaths in the PCI group. Of these deaths, 75% were caused by cardiac causes (12 cases), and 25% were due to extra-cardiac causes (cancer and etc). There were 19 deaths in the CABG group. While 42.1% of these deaths were due to cardiac causes (12 deaths), 57.9% to extra cardiac causes (cancer and etc.) (p = 0.05).

DISCUSSION

We examined 405 patients with DM out of 1643 patients presenting with ACS with regard to the applied revascularization treatment. This real-world setting of 183 patients with PCI and 222 patients with CABG revealed that there was no difference in terms of primary endpoints between the 2 groups during the 5-year follow-up period. The primary endpoints including death, MI, and stroke were observed in 16.9% of the PCI group and in 14.9% in the CABG group (p = 0.582). Meanwhile, a stroke was occurred in 1.1% of patients in the PCI group and 4.9% of patients in the CABG group (p = 0.05).

In the FREEDOM trial that enrolled 1900 patients with DM and CAD without main left coronary artery involvement, first-generation drug-eluting stents were used and CABG was compared with PCI[13]. At 5-year follow-up, all-cause mortality, non-fatal MI, and stroke was observed in 26.6% in the PCI group, and 18.7% in the CABG group (absolute difference of 7.9%, 95% CI 3.3–12.5%, P = 0.005). Mortality (16.3% in the PCI group vs. 10.9% in the CABG group; absolute difference 5.4%, 95% CI 1.5–9.2%, P = 0.049) and MI (13.9% in the vs. 6.0% in the CABG group, P <0.001) was higher, however the stroke rate was (2.4 vs. 5.2%; P = 0.03), lower in the PCI group. Because of the implementation of drug-eluting stents a low percentage difference was observed. The advantage of the BAR trial was mainly related to the use of internal mammarian grafts in most of the patients [14]. In VACARDS trial (Coronary Artery Revascularization Diabetes Study) in the patients with Diabetes and advanced Coronary Artery Diseases, PCI and CABG groups were compared in the United States [combined mortality

risk and non-fatal MI was 18.4% in the CABG group, while it was 25.3% in the PCI group (HR 0.89, 95% CI 0.47–1.71, P <0.05)] [15].

In contrast to these studies, we did not see any differences in the 5–year, mortality, and the MACE percentage between two groups in our study. The contrary results we observed were probably due to the use of new-generation drug-eluting stents in our study. Unlike the first-generation drug–eluting stents, the polymer portion of these stents, is very thin, and completely absorbable within the 6 months of implantation[16] which translates in to a significant reduction of MI and death both in the short and long term follow-up after the procedure. In contrast to the Freedom trial, our population included patients with acute CAD and patients with a more complex coronary anatomy. In contrast, in our study, we found that MI reductions was lower in the CABG group than in the PCI group (p=0.034). Our result is consistent with the results obtained in the diabetic subgroup of the SYNTAX trial [11].

The use of LIMA graft was low, i.e., 47.8%, in SYNTAX group, while our study found that the use of LIMA was 96%. Overall, 452 patients with DM and multi-vessel CAD were studied in a subgroup analysis of the SYNTAX trial. The 5-year follow-up showed no difference in overall outcome, including stroke, MI and all-cause mortality. Repeated revascularization in patients with DM was higher in the PCI group than in the CABG group. (HR 2.01, 95% CI 1.04–3.88, P <0.001). SYNTAX score was low, (≤22) (38.5 vs. 18.5%, respectively, P = 0.014) and moderate (23 - 33) (27 vs. 13.4%, respectively, P = 0.049 in diabetic patients) and repeated revascularization was higher in the PCI group than in the CABG group[4,17].

Our results also showed that the repeated revascularization was higher in the PCI group (18.4%) than in the CABG group (10.8%). p=0.012. The first-generation drug –eluting stent was used in a meta-analysis of 4,552 patients, which included four randomized trials. PCI and CABG were compared in these patients with diabetes. In the PCI group which used first-generation drug eluting stents, mortality, MI and repeated revascularization were higher (RR 1.51, 95% CI 1.09–2.10; P <0.01 in the first generation drug –eluting stents), but the stroke rate was lower (P <0.01), compared with CABG group (2.3 vs 3.8%, RR 0.59, 95% CI 0.39– 0.90; P <0.01) [18].

Sensitivity analysis revealed the superiority of the CABG in patients with a high SYNTAX score compared to the first-generation medicinal stents for MACE percentages. The recent meta-analysis has revealed that the superiority of CABG over PCI in diabetic patients might be reduced by the use of everolimus-eluting stents [19,20]. This, again supports the results obtained in our study in the favor of the use of new-generation drug-eluting stents. In another trial of 11,518 patients, patients with multiple vascular coronary arteries stenosis and the main coronary artery stenosis were studied. This study showed a significant difference in the PCI group (11.2%) and CABG (9.2%) in all-cause mortality (P = 0.0038), whereas in diabetic patients this difference was more pronounced (10.7% in the CABG group vs. 15.7% in the PCI group, respectively; P = 0.0001). However, no significant difference between the groups was observed in non-diabetic patients (8.4% in the CABG-group vs. in the PCI-group 8.7%; respectively; P = 0.81) [21, 22].

Since the use of drug-eluting stents and the evidence of their superiority over free drug-eluting stents, many studies have been published comparing PCI and CABG. In a randomized controlled study conducted by BEST researchers, showed that, everolimus eluting stents were never left behind in comparison with CABG. Although the initial stage of the study was slow, the results of all 800 patients had been completed. The mortality due to MI, or the primary outcome of a two-year target vascular revascularization, was 11% in the PCI group and 7.9% in the CABG group in this study. During 4.6 years of follow-up, this difference was significant (15.3% was in the PCI-group and 10.6% - in the CABG-group)[17].

The SYNTAX trial was conducted on 1,800 patients. It has shown that PCI is not inferior to CABG. Major Cardiac incidents or cerebral events were significantly higher (12.8%, vs. 12.4% for CABG) in the PCI group after the 12-month follow-up compared to the CABG group. Authors have suggested this difference as a result of repeated revascularizations (13.5% for the PCI group and 5.9% for the CABG group)[11,23]. The 1-year follow-up of the SYNTAX trial yielded several different results in subgroup analysis. Of these, the percentage of MACE in diabetic patients with multi-vessel diseases was higher in the PCI group compared with the CABG group. Although this difference persisted in non-diabetic patients, it was not statistically significant. The SYNTAX trial

showed an increase mortality both in PCI and CABG groups in diabetic patients compared to non-diabetics. In this study, in both diabetic and non-diabetic patients with complex coronary anatomy (SYNTAX score of more than 33) mortality was higher in the PCI group when compared to the CABG group. Repeated revascularization was more common in the PCI group in both diabetic and non-diabetic patients as compared to the CABG group[23, 24].

In contrast to Freedom and SYNTAX trials, in which the first-generation drug-eluting stents have been used for 5 -year follow-up, in our study using only new-generation drug -eluting stents, there was no difference between the PCI, and the CABG groups for the MACE percentage (p = 0.616). However, as in both trials, repeated revascularization was greater in the PCI group than in the CABG group (p = 0.012). Meta-analysis of all these studies have also shown that the stroke rates are higher in the CABG group compared to the PCI group[25]. As in the case of BARI 2 Diabetes (Bari-2D), adherence to treatment in our study was strictly continued during the follow-up period[26].

Our study had several limitations. First is the single center enrollment. In addition, if there were more patients, we could achieve more comprehensive results, and we could also evaluate subgroups. Lack of randomization to either PCI or CABG might be accepted as a limitation. However, retrospective enrollment of our patients is a strength of the study as it represents the real-life clinical settings. In baseline evaluation, the CABG group had more hypertension and peripheral vascular disease. This difference could affect the overall results, and therefore might be accepted as a limitation. The high stroke rate in CABG patients might be due to the high proportion of hypertension; however, as the whole study population was followed up by the same physician the blood pressure was on target in most of the study population.

This real-world setting of diabetic patients showed that there was no difference in all-cause mortality between the PCI and the CABG groups during 5-year follow-up. Repeated revascularization and MI were more frequent in the PCI group than in the CABG group. In contrast, the stroke rates were higher in the CABG group. These results imply that new generation drug eluting stents have improved the long-term outcomes of diabetic patients presenting with ACS.

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