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Review

Long-term clinical results of saphenous vein bypass graft lesions treated with bare-metal stents and drug eluting stents

Abdulmelik Yıldız [a,*], Cennet Yıldız [b]

[a] Avrupa Şafak Hospital, Istanbul, Turkey
[b] Tekden Hospital, Istanbul, Turkey

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ABSTRACT

Objective: To evaluate the long-term clinical results of bare stents (BMS) and drug eluting stents (DES) for the treatment of saphenous vein graft (SVG) lesions, to examine the efficacy and safety of both and to determine the parameters that have predictive value for long term clinical results.
Methods: Between 2009 and 2011, the long-term results were examined and compared respectively in 107 patients with SVG lesions on whom revascularization was applied using BMS or DES.
Results: The long-term results of BMS (n: 56) and DES groups (n: 51) were compared (average follow-up time for both groups: 22.1 ± 10.7 months). At one-year follow-up, the BMS group had higher target vessel revascularization (TVR) (33.9% vs 11.8%, p = .01) and major adverse cardiac events (MACE) (35.7% vs 15.7%, p: .02) compared to the DES group. There were no significant differences in myocardial infarction (MI) and mortality rates between the two groups. At a median follow-up of 2 years, there were no significant differences in composite MACE, TVR, MI and mortality rates between the two groups. Event free survival at 1 and 2 years was 84.3%, 66.7% vs 64.3%, 50% for DES and BMS group, respectively.
Conclusion: At one year follow-up, patients receiving DES had significantly better clinical outcomes than their BMS counterparts. However, long term outcomes among the two groups were similar.
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Contents

Introduction

Since the first coronary artery bypass operation by Favaloro in 1968, the improvements in revascularization have been continuing to accelerate.[1] However, the fragile structure, degeneration and occlusion that were seen in SVG have emerged as long-term problems. The development of stenosis or occlusion in SVG in 15% during the first year and 50% in 10 years has revealed that new techniques must be used.[2] The initial implementation of balloon angioplasty has been superseded by direct stent implantation due to low success, high restenosis rates and increases in MACE in the former. In 1998, Figulla et al. obtained better results in clinical applications via introducing direct stent technique without angioplasty.[3] Advances in stent technology paved the way for

* Corresponding author at: Seyit Nizam mah. Balikli Çırpıcı Yolu Kiptaş Merkez Evleri A7 Block No: 25 Zeytinburnu, Istanbul, Turkey.
E-mail address: drmelik@hotmail.com (A. Yıldız).
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the use of DES as well as BMS in SVG lesions. The studies revealed conflicting results on BMS and DES application results in saphenous vein grafts. In the short term, SVG revascularization with BMS resulted in high rates of restenosis.[4,5] Although short term restenosis rates were found significantly lower with DES, the studies reported that this benefit disappeared in the long term and the mortality rate increased.[6–9] Although there is consensus on short term results, more comprehensive research is needed on long term results. In this study, we compare the long term results of BMS and DES implantations in saphenous vein grafts, and determine the parameters that have predictive value for MACE.

Methods

Between 2009 and 2011, 107 patients who received percutaneous coronary intervention (PCI) due to SVG lesions were retrospectively analyzed. The investigations were performed by two experienced cardiologists. Patient data was obtained from medical records, telephone contact and outpatient examinations. After a detailed history had been taken, their physical examinations were performed. All patients, who underwent at least one exercise stress test and myocardial perfusion scintigraphy (99mTc-MIBI) for the investigation of ischemia were included in the study. Patients who had signs of ischemia received coronary angiography as the standard approach. The patients were administered 325 mg/day of aspirin, 600 mg clopidogrel, if the patients are not on it, and 100 units/kg of heparin administered before the procedure to reach the target clotting time (ACT) of 250–300 s. Biochemical analysis of blood samples is held before the procedure. 56 applied BMS and 51 patients applied DES. The dates when the first and the last applications done to the patients are recorded and their total monitoring times were calculated. All patients received clopidogrel and aspirin for 1 year and only aspirin after that.

Definitions

MACE was defined as a sum of cardiac death, myocardial infarction, target vessel revascularization (TVR). Target lesion revascularization (TLR); revascularization procedure for lesions that have more than 50% stenosis within the stent, 5 mm proximal or distal to the stent. Stent thromboses were evaluated according to the criteria defined by the Academic Research Consortium.[10] The diagnosis of myocardial infarction required 2 of the following: 1) prolonged (>30 min) chest pain; 2) a rise in creatine kinase levels more than twice the local upper normal value (with abnormal MB fraction); and 3) development of persistent ischemic electrocardiographic changes (with or without new pathological Q waves). Deaths of unknown etiology are considered to be cardiac deaths. Procedural success was considered to be <20% of residual stenosis and TIMI (Thrombolysis In Myocardial Infarction) grade III flow.[11]

Table 1
Baseline clinical characteristics.

Parameters	BMS group (n: 56)	DES group (n: 51)	p
Age (years)	63.1 ± 6.8	64.2 ± 8.1	0.747
Male, n (%)	44 (78.6)	36 (70.6)	0.379
Female, n (%)	12 (21.4)	15 (29.4)	
Hypertension, n (%)	38 (67.8)	31 (60.7)	0.874
Diabetes mellitus, n (%)	18 (32.1)	19 (37.2)	0.252
Smoking, n (%)	29 (63.0)	5 (55.6)	0.719
SVG age (years)	8.0 ± 6.3	7.5 ± 3.6	0.879
SVG vessels, n	3.4 ± 0.7	3.3 ± 1.3	0.478
Beta blocker, n (%)	42 (75)	40 (78.4)	0.885
Statin, n (%)	41 (73.2)	40 (78.4)	0.775
Hematologic parameters			
MPV (μm^3)	8.7 ± 9	8.9 ± 1.5	0.737
PDW (%)	16.3 ± 11.0	13.4 ± 1.2	0.06
NLR	2.7 ± 1.2	2.2 ± 0.6	0.323
RDW (%)	14.1 ± 1.8	12.9 ± 1.8	0.232
Platelet count (10^9/l)	237.3 ± 56.3	241.0 ± 65.8	0.637

SVG: saphenous vein graft, MPV: main platelet volume, PDV: platelet distribution volume, NLR: neutrophil lymphocyte ratio, RDW: red cell distribution wide[9]; BMS, bare metal stent; DES, drug eluting stent.

Table 2
Lesion and procedural characteristics.

Parameters	BMS group (n: 56)	DES group (n: 51)	p
Number of stents, n (%)	1.8 ± 0.9	1.7 ± 0.9	0.688
Diameter stenosis, %	86.0 ± 11	95.0 ± 0.3	0.548
Stent diameter, mm	3.2 ± 0.6	3.1 ± 0.5	0.791
Stent length, mm	17.5 ± 6.0	25.8 ± 11.9	**0.030**
Maximum balloon pressure (atm.)	13.3 ± 1.6	14.0 ± 4.2	0.718
No reflow, n (%)	4 (7.1)	3 (5.8)	0.771
Angiographic success, n (%)	54 (96.4)	50 (98)	0.876

BMS, bare metal stent; DES, drug eluting stent.
Bold values indicate significance at $p < 0.05$.

Statistics

Continuous variables are expressed as mean ± SD. Categorical variables are expressed as percentages. To compare parametric continuous variables, Student's *t*-test was used; to compare nonparametric continuous variables, the Mann Whitney *U* test was used; and to compare categorical variables, chi-squared test was used. Multivariate logistic regression analysis was used to identify the independent predictor of MACE. Event-free survival curves were generated by the Kaplan–Meier method and differences in survival were compared using log-rank test. All variables showing significance values less than 0.05. Two-tailed p values less than 0.05 were considered significant and the confidence interval was 95%. All statistical studies were carried out using the SPSS program (version 22.0; SPSS Inc., Chicago, Illinois, USA).

Results

Clinical and demographic characteristic of patients are shown in Table 1. In total of 107 patients (27 women, 80 men, mean age: 62.3 ± 7.3 years) were included in the study. There were similarities between these two groups in terms of demographic and clinical characteristics and medical treatment. There were no statistical differences between the groups in terms of age, gender, hypertension, diabetes, and smoking. Average age of SVG was 7.73 ± 4.6 years. There was no significant difference between the two groups in terms of bypass graft age and number of grafts.

Table 2 shows lesion and procedure characteristics. The number of stents implanted per patient was 1.65 ± 8.9, with an average diameter of 3.04 ± 0.5 mm. Stent length in the DES group was significantly longer than that in the BMS group (25. 8 ± 11.9 mm vs. 17.5 ± 6.0 mm, $p = .03$). Maximum inflation pressure (pressure: 13.8 ± 2.0 atm.)

Table 3
Clinical outcomes at long term follow-up.

Parameters	BMS group (n: 56)	DES group (n: 51)	p
One year outcomes			
Composite MACE, n (%)	20 (35.7)	8 (15.7)	0.02
TVR, n (%)	19 (33.9)	6 (11.8)	0.01
Myocardial infarction, n (%)	5 (9.1)	4 (8)	1.00
Mortality, n (%)	2 (3.6)	1 (2)	1.00
Total follow up time outcomes			
Composite MACE, n (%)	30 (53.6)	18 (35.3)	0.08
TVR, n (%)	22 (39.3)	14 (27.5)	0.223
Myocardial infarction, n (%)	9 (16.1)	7 (813.7)	0.791
Mortality, n (%)	3 (5.4)	2 (3.9)	1.00

MACE: major adverse cardiac event, TVR: target vessel revascularization; BMS, bare metal stent; DES, drug eluting stent.

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