

Clinical Research

Long-Term Outcomes of Percutaneous Coronary Intervention with Drug-Eluting Stents Versus Bare-Metal Stents in Saphenous Vein Graft Lesions: A Single Center Experience*

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ABSTRACT

Objective: There is controversy data about the use of drug-eluting stents versus bare-metal stents in saphenous vein graft lesions. Our purpose was to compare the outcomes of patients receiving drug-eluting stents or bare-metal stents in saphenous vein graft percutaneous coronary interventions.

Material and Method: All patients undergoing saphenous vein graft percutaneous coronary intervention with a drug-eluting stent or bare-metal stent alone from January 2013 to December 2017 at our center were assessed retrospectively. Major adverse cardiac events including myocardial infarction, target vessel revascularization and death were recorded at follow up period.

Results: Ninety two patients included the study. Of these, 72 patients received a drug eluting stent and 20 patients had a bare metal stent. The median follow-up was 29 (range 0-66) months. There were no different outcomes for myocardial infarction, death and target vessel revascularization between drug eluting stent and bare metal stent. The rate of major adverse cardiac event -free survival was %71.3 in the drug eluting stent group and %71.8 in the bare metal stent group (p =0.660).

Conclusion: There was no significant difference in long-term outcomes between drug eluting stent and bare metal stent in saphenous vein graft percutaneous coronary interventions in our real world experience. However, more cases and long-term follow-up are warranted.

Keywords: Saphenous Vein Graft, Percutaneous Coronary Intervention, Long-term Outcomes.

ÖZET

Safen Ven Greft Perkütan Koroner Girişimlerinde İlaç Kaplı Stentlerle Çıplak Metal Stentlerin Uzun Dönem Sonuçları: Tek Merkez Deneyimi

Amaç: Safen ven greft lezyonlarında ilaç kaplı ya da çıplak metal stent kullanımıyla ilgili sonuçlar tartışmalıdır. Bizim çalışmamızın amacı çıplak metal stent ve ilaç kaplı stent kullanılan safen ven greft perkütan koroner girişim sonuçlarını karşılaştırmaktır.

Gerçek ve Yöntem: Merkezimizde Ocak 2013-Aralık 2017 tarihleri arasında ilaç kaplı veya çıplak metal stent ile safen ven greft perkütan koroner girişim yapılmış tüm hastalar retrospektif olarak değerlendirildi. Miyokard infarktüsü, hedef damar revaskülarizasyonu ve ölümü içeren majör kardiyak olaylar açısından karşılaştırma yapıldı.

Bulgular: Çalışmaya 92 hasta dahil edildi. 72 hastada ilaç kaplı stent ve 20 hastada çıplak metal stent kullanılmıştı. Ortalama takip süresi 29 (0-66) aydı. İlaç kaplı stent ve çıplak metal stent arasında myokard infarktüsü, ölüm ve hedef damar revaskülarizasyonu açısından fark yoktu. Olaysız sağkalım oranı her iki grupta benzerdi. (%71.3 ilaç kaplı stent grubu, %71.8 çıplak metal stent grubu, p =0.660).

Sonuç: Gerçek yaşam verilerimizde safen ven greft perkütan koroner girişimlerinde ilaç kaplı stentlerle çıplak metal stentler arasında uzun dönem klinik sonuçlarda anlamlı bir fark yoktu. Bununla birlikte, daha fazla vaka ve uzun süreli takipler gereklidir.

Anahtar Sözcükler: Safen Ven Greft, Perkütan Girişim, Uzun Dönem Sonuçlar.

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Saphenous vein graft (SVG) stenosis after coronary artery bypass graft surgery (CABG) is common and about 40% of grafts being occluded at 10 years (1). Percutaneous coronary intervention (PCI) of SVG is preferred therapeutic option because of high operative risk of redo-CABG (2). Drug-eluting stents (DES) have been demonstrated to be safe and effective in native coronary vessels and DES are superior to bare metal stents (BMS) in most lesion types (3). Randomised studies have been reported conflicting results about

DES use in SVG PCI (4-6). We aimed to report long-term outcomes of our single center experience with DES versus BMS in SVG PCI.

MATERIAL AND METHOD

In this retrospective study we evaluated 92 patients undergoing SVG PCI at our hospital from January 2013 to December 2017. Patients were evaluated in the study under an institutionally approved protocol.

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Patients who treated with DES or BMS alone included the study. Patients who had stents placed in native vessels during the same procedure and patients who received both DES and BMS in the same vessel were excluded. Those who were lacking data in the follow-up period were not taken into the study.

Baseline clinical characteristics, angiographic characteristics and PCI data were identified from computer database of our institution. Clinical follow-up data were confirmed by telephone contact. Survival status checked by using National Death Notification System. The events analyzed in this study included death (cardiac and noncardiac), myocardial infarction (MI) (Q wave and non-Q-wave), target vessel revascularization (TVR) (percutaneous). All deaths were considered cardiac unless otherwise documented. MI was defined as elevation of hs troponin upper limit of normal in addition to electrocardiographic changes. TVR was defined as repeat revascularization within the treated vessel. Major adverse cardiac events (MACE) were defined as cardiac death, MI and TVR.

Statistical analysis: All statistical analyses were performed using the SPSS 25 (SPSS INC, Chicago, Illinois, USA). Categorical variables were expressed as frequencies and continuous variables as mean \pm Standard deviation. Kaplan-Meier survival curves used to assess MACE-free survival times and log-rank statistics were used to test survival time differences between groups. A calculated difference of $p < 0.05$ was considered to be statistically significant.

RESULTS

Baseline clinical characteristics of the study group are summarized in table 1.

Table 1. Baseline characteristics of patients according to stent type.

Variables	DES (n =72)	BMS (n =20)	p value
Age, yr	64,9 \pm 8,2	69,2 \pm 10,1	0,053
Male vs. Female, n (%)	64 (%88,8)	19(%95)/1(%5)	0,678
HT, n (%)	41 (%56,9)	13 (%65)	0,442
DM, n (%)	32 (%45,7)	5 (%27,7)	0,192
Glucose, mg/dL	148,1 \pm 77	133,4 \pm 53,3	0,471
Creatinine, mg/dL	1,1 \pm 0,4	1,3 \pm 1,1	0,454
LDL, mg/dL	126,7 \pm 45,7	100,2 \pm 29,2	0,010
Hemoglobin, g/dL	13,5 \pm 1,6	13,2 \pm 2,09	0,584
LVEF, %	46,7 \pm 12,1	46,4 \pm 16,1	0,955
Treated Graft age, yr	9,8 \pm 5,9	13,6 \pm 6,5	0,131
Stent diameter, mm	2,8 \pm 0,3	3,2 \pm 0,7	0,021
Medications			
ASA, n(%)	69 (95,8)	18 (90)	0,873
Clopidogrel, n(%)	67 (93)	16 (80)	0,341
Ticagrelor, n(%)	3 (4,1)	2 (10)	0,265
Beta-blocker, n(%)	54 (75)	12 (60)	0,547
Statin, n(%)	71 (98,6)	18 (90)	0,409

Abbreviations: DM, Diabetes mellitus; HT, hypertension; LDL, low-density lipoprotein; LVEF, left ventricular ejection fraction; ASA, Acetylsalicylic acid.

LDL levels were significantly higher in the DES group (126.7 \pm 45.7 vs. 100.2 \pm 29.2, $p = 0.01$). Compared to the BMS group, the DES group had a smaller stent diameter (2.8 \pm 0.3 mm vs. 3.2 \pm 0.7mm, $p = 0.021$) and a longer stent length per lesion (21.6 \pm 7.3mm vs.

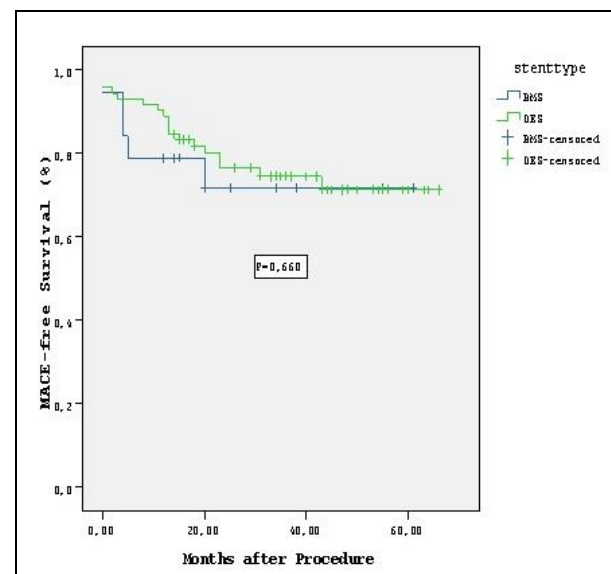
16.9 \pm 5.1, $p = 0.002$). The median follow up period was 29 (range 0-66) months. Clinical outcomes during follow up period was showed in table 2.

Table 2. Clinical outcomes during follow up period.

Variables	DES(72)	BMS(20)	p value
MACE,n (%)	18(25%)	5(25%)	>0.05
MI	4 (5.5%)	0	>0.05
TVR	13(18%)	3(15%)	>0.05
Death	6 (8.3%)	2(10%)	>0.05

MACE, major adverse cardiac events; MI, myocardial infarction; TVR, target vessel revascularization.

The MACE rate was %25 in each group ($p > 0.05$). There were no statistically significant differences in the incidence of MI, TVR and all cause-mortality between two group. The rate of MACE-free survival was 71.3% in the DES group and 71.8% in the BMS group ($p = 0.660$) (Figur 1).



Figur 1: Kaplan-Meier survival curves for freedom from major adverse cardiac events at follow up.

DISCUSSION

We did not find a significant difference between DES and BMS in the incidence of MI, TVR and all-cause mortality during the follow up period among patients undergoing stenting of SVG lesions.

Randomised controlled trials done to date reported conflicting results (some showed benefit with DES and some showed harm). Brilakis et al. (7) examined the risks and benefits of DES versus BMS in a prospective, double blind, randomised trial including 597 patients. They found no significant differences in outcomes between those receiving DES and BMS during 12 months of follow-up. Kheiri et al. (8) reported a meta-analysis of all randomized clinical trials comparing the outcomes of DES with BMS in SVG percutaneous coronary interventions. They showed the use of DES in SVG lesions was associated with lower short-term MACE, TLR and TVR in comparison with BMS but

there were no significant differences with long term follow up. Ha et al. (9) reported that DES is associated with a reduction in repeat revascularization compared with BMS and similar MACE rates in their updated systematic review and meta-analysis of randomized trials. In our study our results are in concordance with most of the literature.

It is known that SVG PCI is associated with worse clinical outcomes compared to native vessel PCI due to pathology of SVG lesions which are characterized by

diffusely friable atherosclerotic plaques with thin fibrous caps and high thrombotic burden (10). This mechanism could explain the absence of benefit with DES. Our study has several limitations. It is a retrospective single-center study with a relatively small sample size. Therefore our results may not reflect entire population. The type of used DES which might affect the clinical outcomes not specified. Also, mostly males were involved in the study. Sex differences are unlikely to affect the clinical outcomes of the study.

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